Imperial College London

Sectoral Systems of Innovation and the UK's Competitiveness:

The UK MedTech Sector

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Executive Summary

The UK Medical Technology (MedTech) sector generates tremendous societal impact by producing a wide variety of life-saving and life-improving technologies. The NHS and healthcare systems around the world depend on these devices every day. While the successes of the UK Biopharmaceutical sector are well-known, the MedTech sector has received less attention, and in fact has not been well characterised for quantitative economic impact. In this report, we provide a database of the UK MedTech sector and analyse it for important indicators of success. We conducted interviews with key sector stakeholders to identify opportunities for improving or growing the sector.

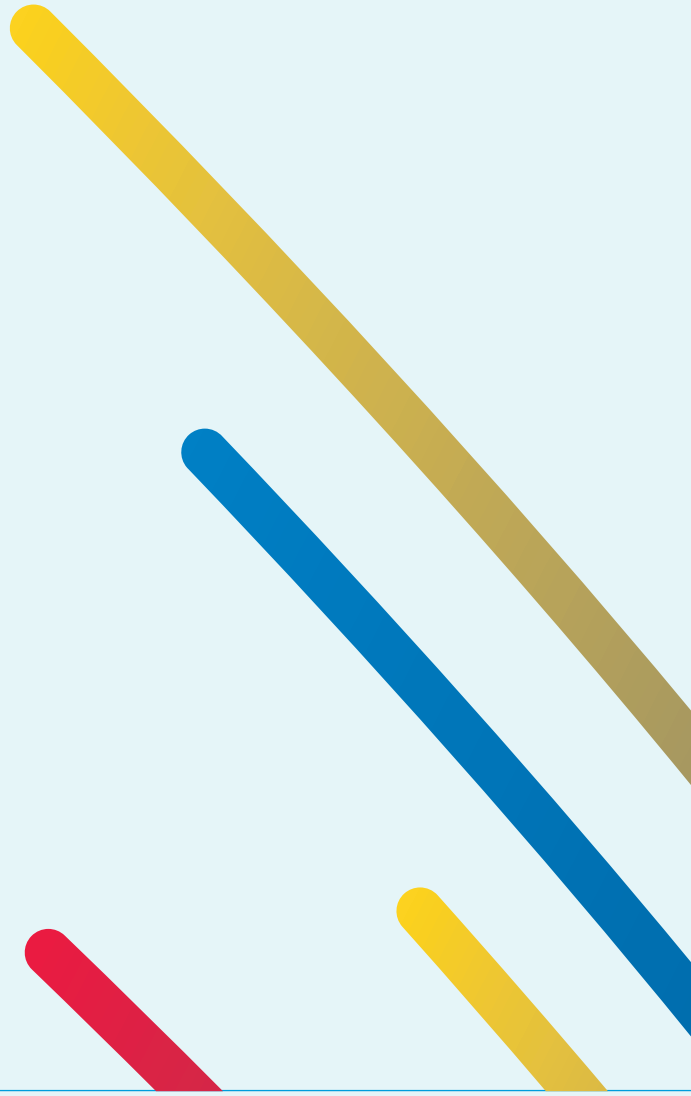
Information from three different databases was combined, yielding a first list of 3014 firms. Using a series of filtering steps, including manually certifying each firm, we finalised the database to include 1640 firms, characterised by 179 columns of employment and economic data. We have limited our definition of MedTech to companies producing devices for which regulatory approval is required for marketing.

The UK MedTech sector is mostly made up of SMEs seeking opportunities to grow with either grant or investor funding to achieve regulatory approval to market their technologies. For those companies who have succeeded, turnover, wages and exports grew by 14%-19% compound annual growth rate (CAGR) in 2016-2020. Gross Value Added (GVA) to the economy stands at £13.5B, with a CAGR of 19%. GVA/employee is approximately £100k. University spinouts form an important basis for the sector, and MedTech is the most common category for these firms.

While these are encouraging numbers, stakeholders identified many missed opportunities to improve sector performance. The issue of primary concern is the UK's post-Brexit approach to medical device regulation, which still lacks clarity. There are multiple associated challenges, including a transition in the EU's regulatory practices and availability of relevant expertise to process applications for regulatory approval.

Our recommendations include:

- **Regulatory system:** Finalise the post-Brexit transition for the UK's regulatory body, the MHRA. Further develop and clarify the fast-tracked route of devices approved by the US, EU, and Japan.
- **Funding:** Increase MedTech-specific grant funding so that more projects deemed worthy of funding by expert reviewers can succeed. Continue and enhance incentives for investment attractiveness such as SEIS/EIS and R&D Tax Credits.
- **NHS procurement of innovative MedTech devices:** Review and reform procurement practices from the caregiver level upwards. Encourage grass-roots innovation adoption by partnering with early stage MedTech firms. Encourage and resource NHS staff to identify and address unmet clinical needs.
- **Education:** Encourage the establishment of courses that include regulatory training in relevant technology areas. Rehabilitate technology transfer policies and procedures so that university spinouts are well set up for success.



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Section 1: Background

What is MedTech?

When clinicians are faced with a medical problem, they need solutions. The two important industrial sectors that supply these solutions are Biopharmaceuticals and Medical Technologies (MedTech) [1]. The nature of a particular disease plays a big role in determining whether the available solutions are Biopharmaceutical or MedTech. For some diseases, there can be a mixture of solutions. Heart disease is a good example. There are about the same number of pharmaceutical solutions (beta blockers, ACE inhibitors, statins) as there are MedTech (pacemakers, stents, prosthetic heart valves).

The primary reason that Biopharmaceuticals and MedTech are considered separate sectors is that they are based on different underlying sciences. Biopharmaceuticals rely heavily on biology and chemistry, with incorporation of materials science. MedTech products are based not only on biology, but also physics, chemistry, mathematics, and draw heavily on concepts used in engineering disciplines (mechanical, electrical, chemical, materials, design, computing, optics, etc.). Many developers of MedTech products now receive their training in the recently emerged field of biomedical engineering.

The great variety of MedTech products spans those mentioned above, hip implants, contact lenses, prostheses for amputees, ventilators, plasters, tongue depressors and knee replacements. Obviously, some of these technologies present more risk to patients than others. The MedTech sector is thus heavily regulated by governmental bodies with the authority to pursue legal prosecution for negligent failures. The UK's Medicines and Healthcare products Regulatory Agency (MHRA), along with most similar organisations in other countries, use three levels of classification for MedTech products. Class I products are the least risky, then Class II products are those that can cause moderate harm. Class III products are those that may lead to great harm or death if they fail.

For the purposes of this report, we limit our definition of MedTech to *products that require some level of regulatory approval to be placed on the market*. The key factor that determines if a product requires regulatory approval is whether its manufacturer makes medical claims about its performance. There are many related products that can perform health-related functions (such as smartphone apps that report number of steps taken), but if they do not make medical claims then they typically will not require regulatory approval. The broader category of HealthTech would encompass these products plus MedTech. We also incorporate diagnostic devices into our definition of MedTech, again if they require regulatory approval. Our reasoning behind this limitation is that all aspects of business planning are centred on the need for regulatory approval (which likely will take years to achieve). This includes intellectual property strategies, funding requirements and even the way the technical design details are documented. The need for regulatory approval can also serve as a barrier to competition. If a competitor wishes to enter the market with a "me-too" technology, they must overcome both the IP portfolio of the preceding technology and regulatory requirements.

Goals of this report

Despite the importance of the MedTech sector in supplying products to the NHS and other healthcare systems worldwide, the field is somewhat under-recognised. The UK MedTech sector has not previously been quantified and analysed in a meaningful way [2,3]. A primary purpose of this study is therefore to establish and analyse a database of important economic measures for UK-based MedTech companies. Then, alongside a wide-ranging survey of those companies and related stakeholders, identify barriers to, and opportunities for growing the sector. These findings can hopefully encourage steps towards the UK having a more competitive, higher value adding, MedTech sector.
We utilised three main methods of analysis:

- Assembling a novel UK MedTech database to assess the current profile of the sector.
- Carrying out interviews with a variety of key sector players to gain insight from those who would be directly affected by our proposed opportunities. This was also crucial to planning our data collection strategy.
- Extrapolating and analysing data from our database and other sources. This included financial, regional, and funding data.

Current challenges to the UK MedTech sector

The UK's MedTech sector is undergoing an important transition since Brexit. The MHRA is replacing the CE mark with a new UKCA mark. Concurrently, the EU began a transition period in 2021 from the Medical Devices Directives (MDD) to the stricter Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR).

The UKCA mark currently more closely aligns with the MDD and is currently scheduled to apply from mid 2025. This will also require all pre-existing medical devices to be re-regulated to stay on the market. As of the writing of this report, the MHRA has proposed to accept and fast track devices approved by trusted regulators in the USA, EU, and Japan in an effort to revitalise the UK as a hub for MedTech [4].

However, there is still considerable uncertainty surrounding the MHRA strategy. For example, it is still unclear if MHRA will recognise devices cleared by the FDA through its 510(k) pathway. These uncertainties run the risk of not only damaging the UK MedTech sector, but also severely limiting the number of medical devices available for use in the NHS and private healthcare.

The UK represents approximately 3% of the global MedTech market (Figure 1). Some MedTech multinationals are likely to withdraw their products from the UK and/or not bring their newest technologies to the UK if the MHRA's processes remain incompatible with more widespread systems. This grave danger has been the topic of other recent sector reports and press coverage [5-7]. This also creates an issue for small and medium-sized enterprises (SMEs) and start-ups which are small, newer firms, typically focused on developing and marketing a single product or service.

Other significant challenges to the sector to be discussed in this report include:

- Funding, both grant funding and private investment.
- Accessing the NHS for performing trials and purchasing.
- Translation of devices from research to market.

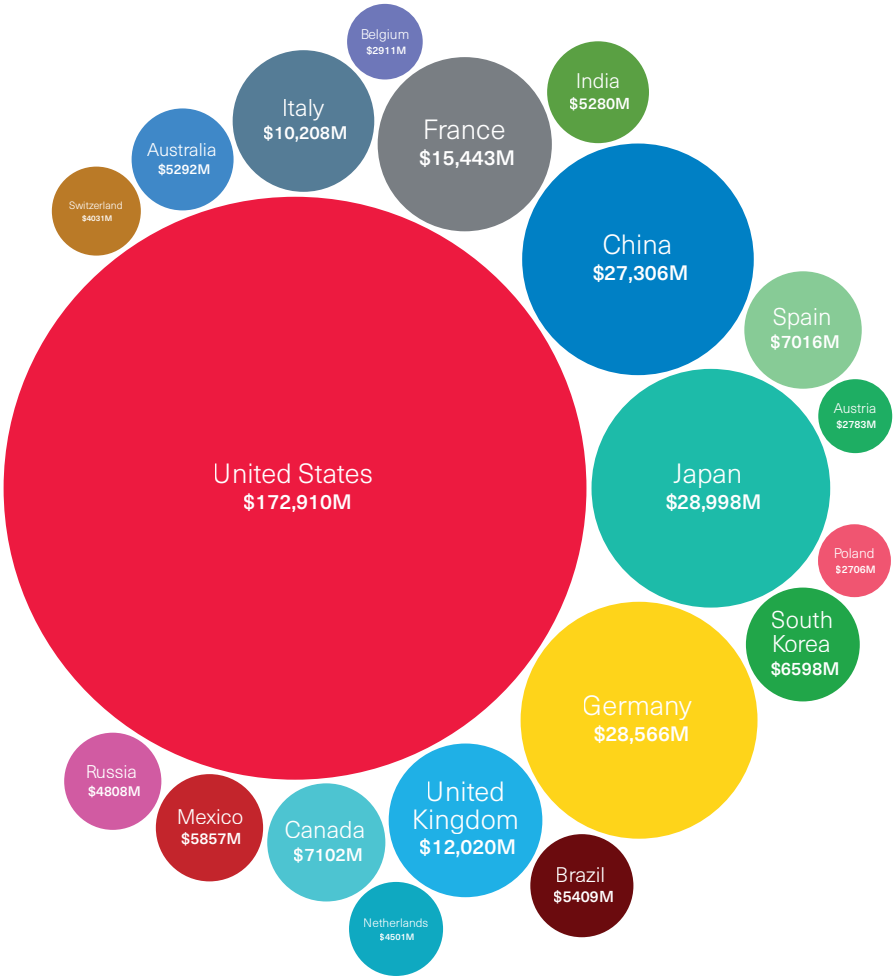

Figure 1: Global MedTech market sizes.

Section 2: Data collection and extrapolation

Imperial College UK MedTech database

A database comprising 1640 MedTech firms was compiled from three sources: the Office for Life Sciences (OLS) [8], Data City [9], and Beauhurst [10].
An initial search of these three databases yielded 3014 firms. The final database was derived by removing duplicates, dissolved firms and those not conforming to our definition of MedTech. Filtering the database in this manner increases its reliability but impedes comparison to other databases which may have not been filtered so strictly.

To our knowledge, this database is the first to characterise both UK MedTech firms and the UK firms which directly serve them. The database has 179 columns of data ranging from descriptive to yearly financial data.

Methodology

Step 1: The first source accessed was OLS from which 744 firms were directly extracted. 218 of these were biopharmaceutical firms and 10 were digital health firms which left 516. Digital health firms, except for those producing regulated devices, do not fall under our definition. The repeats were removed and combined firms were pooled into one entry with one company number. Firms deleted from the database can be found in the "Removed firms" tab with their source as OLS.

Step 2: The 503 firms were then validated using Data City. Eleven firms were confirmed to have been dissolved and were removed from the database, leaving 492 firms. Four of the remaining firms were corrected for having changed their names.

Step 3: The Data City database was then searched for MedTech, returning 1574 results. Thirteen firms were removed as being repeats of OLS firms, leaving 1561 firms. Combining the two sources resulted in 2053 firms.

Step 4: The final source, Beauhurst, was searched for these criteria:

- Firm is clinical diagnostic, medical device, medical instrumentation, or healthcare product.
- Firm is still active.
- Firm is not any of the 88 unrelated sectors specified in Appendix 1.

This returned 1238 firms. We removed 102 firms for not falling under our definition of MedTech, 69 firms for being repeats, and 18 who did not have company numbers.

Step 5: The Beauhurst firms were then validated using Data City, revealing that 29 firms had been dissolved. Combining the remaining Beauhurst firms with the previous two sources gave 3014 firms.

Step 6: All 3014 firms were manually validated one-by-one to ensure that they fit our definition of MedTech. This was done using the Data City description, firm website, or company house description. This process resulted in 1374 firms being removed, for a final tally of 1640 firms.

Step 7: The final steps were to run the database through Data City to collect financial data and format the final database. This final data collection step was carried out on 29 January 2023.

Terminology for classifying firms

The profile of the MedTech sector is strongly influenced by regulatory requirements. For example, the requirements to manufacture devices to ISO or other standards leads most MedTech startups to contract out to other firms that already have the appropriate processes in place. Design firms similarly can supply the required documentation under established Quality Management Systems (QMSs). Regulatory bodies use the term ***Legal Manufacturer*** to refer to the firm whose name is on the label (who likely contracted out some of the development to other firms). Our database includes both MedTech firms that would be viewed as Legal Manufacturers as well as other firms that provide the services required to produce the device.

We will use MedTech Firms to refer to all companies in the database. We will use Original Equipment Manufacturer (OEM) to refer to firms that make products on behalf of Legal Manufacturers.

The firms in our database were manually characterised as one of the following:

- Legal Manufacturer (including digital health)
- Distributor
- Consulting firm (business planning, design/ engineering, regulatory)
- OEM
- Diagnostic service
- Investor
- Testing
- Repair/maintenance service

Limitations and analysis of the database and its sources

Using three different sources, followed by the filtering process outlined above, has resulted in the most reliable database on the UK MedTech sector ever assembled, to our knowledge. Our database is however limited by some characteristics of the underlying databases. One limitation particularly relevant to MedTech is the fact that many firms, especially smaller ones, do not disclose all financial and employment numbers. Second, the OLS database uses SIC codes provided by the firms themselves, and firms are allowed to choose multiple codes. Some firms took this as an opportunity to define their activities as being broader than would be supported factually. Data City classifies firms using artificial intelligence to analyse company websites. Beauhurst was the most robust in terms of identifying MedTech firms through its implementation of multiple filters. However, Beauhurst only tracks firms that qualify as “high growth,” thus excluding larger, more established firms. It is hoped that with these instructions in place, our database can be maintained and developed further.

For financial data, we refer to 2016-2020 data as an indicator of recent growth of the field. More recent data in the database are incomplete and would include fluctuations due to COVID-19.

The major outputs from our database agree roughly, but not exactly[1], with those of the UK’s Office of Life Sciences (OLS) MedTech database and the United Nations Industrial Development (UNIDO) global MedTech database which were the two largest external databases we used as comparison [11, 12]. We compare data from all three where appropriate to illustrate the UK’s global standing in the MedTech sector throughout the report.

1 Because our database was screened manually for non-MedTech companies, its outputs may not be directly comparable to other databases which may not have been subjected to the same level of scrutiny. We also include businesses such as OEMs and consulting firms, which are perhaps excluded from other databases.

Gross value added (GVA) calculations

GVA is a measure of the economic contribution (value generated) of products and services produced and provided by an industry sector. It is a measure of contribution to GDP, defined as the value of the output of the sector minus its consumption (raw materials and overhead) [13].

GVA can be calculated in different ways, depending on the information available (income, output, production, expenditures). Given the information available in our database, GVA was estimated based on income data. Additionally, we have assumed that employee compensation, which should encompass both wages and national insurance contribution, can be approximated by wages. We are also unable to capture self-employment income. We assume that gross operating surplus can be estimated by pre-tax profit, and that there are no production subsidies. We estimate taxes as the difference between pre- and post- tax profits. This effort produced three formulae for GVA.

$$GVA_1 = \text{wages} + \text{pre-tax profit} + \text{tax}$$

This formula was verified by both ONS and Beauhurst representatives. As our database included data for "depreciation of tangibles" which we assume to be a valid approximation of overall depreciation. This led to a second formula,

$$GVA_2 = \text{wages} + \text{operating profit (EBIT)} + \text{depreciation}$$

A third formula based on EBITDA was also used,

$$GVA_3 = \text{wages} + \text{EBITDA}$$

Based on the variety of information available, we could typically only apply one or two of these formulas to an individual company (Table 1). GVA_2 worked for the highest number of firms, so this report will mainly be based on that definition.

Year	Number of firms with data		
	GVA_1	GVA_2	GVA_3
2016	458	828	433
2017	465	870	434
2018	485	910	451
2019	499	964	462
2020	487	1004	451

Table 1: Data availability for each GVA method

Sector stakeholder interviews

We carried out a total of 63 interviews with a variety of key stakeholders to capture issues affecting the UK MedTech sector. These included Legal Manufacturers, OEMs, investors, consultants, and regulators (Table 2). We gathered opinions and quotes for archiving in the "MedTech interviews" supporting material.

Type of firm	Number of interviews
SME Legal Manufacturer	13
Funding body	2
Trade group	10
Regulatory consultant	5
Standards body	3
Government body	6
OEM/Tester/Design firm	10
Incubators/Accelerators	4
Large Legal Manufacturer	2
Law firm	2
Venture Capitalist	3
Clinician	1
Education	1
Insurance	1
Total	**63**

Table 2: Distribution of interviewees

The interviews were structured around a core set of open-ended questions (Appendix 2), and normally lasted between 30-60 minutes. Respondents were also encouraged to provide their own general recommendations.

Section 3: Analysis of Sector GVA

UK GVA

Sector GVA exhibited 19% CAGR between 2016-2020 (Table 3). Although Legal Manufacturers only appear three times in the top firms by GVA (Table 4), they contribute the second largest amount of GVA to the sector (Figure 2). Consultancy firms are the largest in terms of GVA, which may be due to having a smaller reliance on materials consumption.

Year	Sector GVA	
	Total (£B)	Number of firms with data
2016	6.8	828
2017	7.8	870
2018	11.0	910
2019	12.5	964
2020	13.5	1004
CAGR	19%	5%

Table 3: UK MedTech Sector GVA by year

Position	Top company by GVA (2020)		
	Company	Type of firm	GVA (£M)
1	HCL TECHNOLOGIES LIMITED	Design/Engineering consultant	3854
2	SMITH & NEPHEW PLC	Legal manufacturer	1292
3	INTERTEK GROUP PLC	Regulatory consultant	1220
4	IQVIA LTD.	Business consultant	448
5	CONVATEC GROUP PLC	Legal manufacturer	444
6	RANDOX HOLDINGS LIMITED	Legal manufacturer	349
7	L&T TECHNOLOGY SERVICES LIMITED	Design/Engineering consultant	333
8	RENISHAW P L C	OEM	224
9	HCL TECHNOLOGIES UK LIMITED	Design/Engineering consultant	209
10	IQVIA IES UK LIMITED	Business consultant	159

Table 4: Top UK companies by GVA

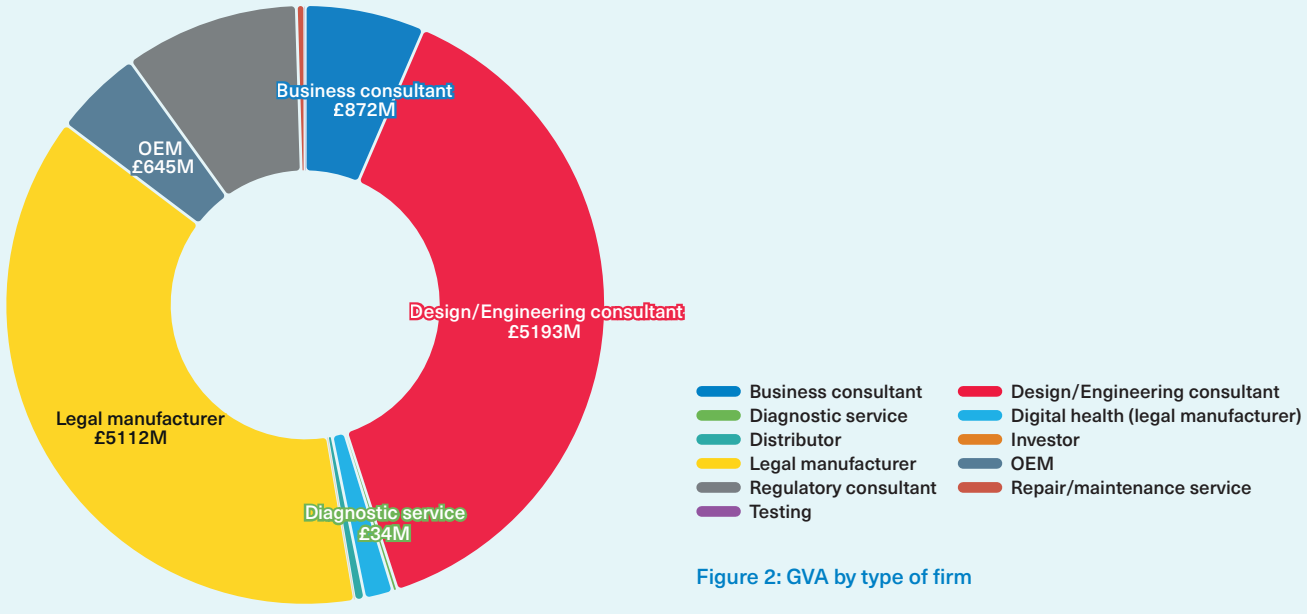

Figure 2: GVA by type of firm

Global comparison of GVA

The UK stands in 6th place on GVA according to UNIDO data (Figure 3). While our data put the UK in 3rd place in the UNIDO table, other countries' data would need to be recalculated to conform to our definitions of MedTech for a proper comparison. The CAGR for GVA is only 2% based on the UNIDO data; much lower than their rates reported for Italy, Singapore, and Denmark (Table 5).

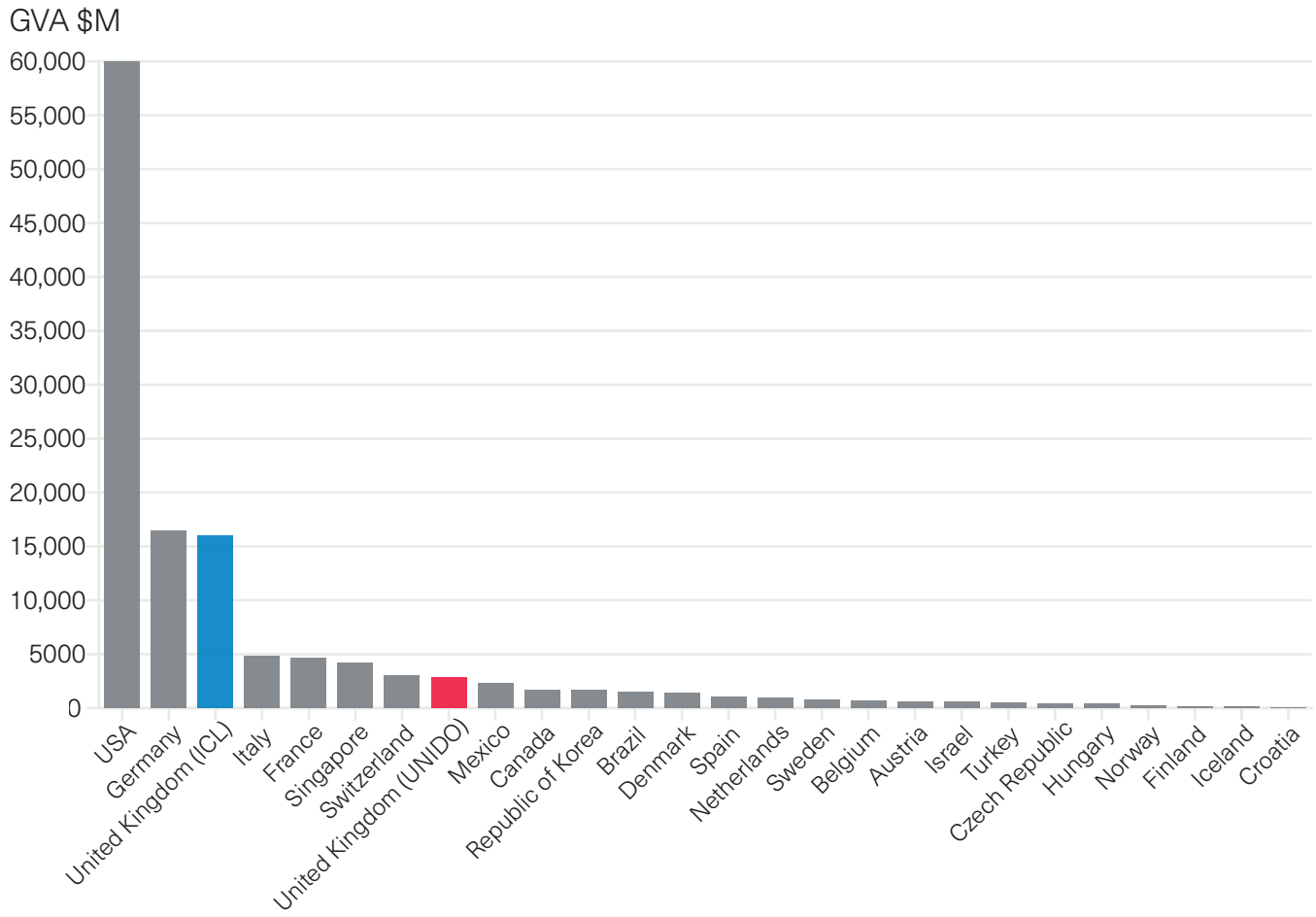

Figure 3: Global comparison of MedTech GVA for 2019 or most recent year available.

Gross value added by the MedTech sector ($M)					
Country	2016	2017	2018	2019	CAGR
USA	60,538	57,728	62,809	60,047	0%
Germany	11,539	14,281	19,422	16,440	13%
United Kingdom	9230	9988	14,711	15,965	20%
France	4344	4715	4881	4650	2%
Italy	3119	4325	4852	4835	16%
Switzerland	2315	2703	2982		9%
United Kingdom	3036	2639	2867		-2%
Singapore	2374	2619	2971	4190	17%
Mexico	1721	1952	2068	2332	11%
Canada	1606	1774	1839	1710	2%
Republic of Korea	1672	1694			0%
Brazil	1263	1508	1453	1495	6%
Denmark	512	1325	1430		41%
Netherlands	820	916	1018	952	5%
Spain	842	904	1012	1019	7%
Sweden	784	751	794	779	0%
Israel	523	605	546		1%
Austria	519	579	586	600	5%
Belgium		507	548	673	10%
Turkey	414	416	438	470	4%
Hungary	415	408	358	406	-1%
Czech Republic	368	394	472	442	6%
Norway	217	181			-6%
Finland	113	116	131	124	3%
Iceland	99	102	108		3%

Table 5: Global comparison of MedTech GVA. Highlighted red value is UNIDO. Highlighted blue value is the Imperial College MedTech database

UK GVA per employee

GVA/employee grew by a CAGR of 13% from 2016-2020 and is currently approaching £100k (Table 6). SMEs contributed 21% of the GVA/employee whereas established firms contributed 61%. This follows from SMEs only contributing 3% of the GVA whereas larger firms contributed 94%.

Year	Sector GVA/employee	
	Total (£k)	Number of firms with data
2016	51	828
2017	51	870
2018	69	910
2019	77	964
2020	83	1004
CAGR	13%	5%

Table 6: UK Sector GVA/employee by year

Position	Top company by GVA/employee method 2 (2020)		
	Company	Type of firm	GVA/employee (£M)
1	HOLOGIC IP LTD	Legal manufacturer	3.95
2	INVIBIO LIMITED	OEM	3.01
3	PORTSMOUTH SURGICAL HOLDINGS LIMITED	Legal manufacturer	2.43
4	BLUE EARTH DIAGNOSTICS LIMITED	Legal manufacturer	1.90
5	AIRCRAFT MEDICAL LTD.	Legal manufacturer	1.09
6	SP 225 LIMITED	Legal manufacturer	0.54
7	THERMO ELECTRON LIMITED	Legal manufacturer	0.53
8	COMARCH UK LTD	Legal manufacturer	0.52
9	VERYAN HOLDINGS LIMITED	Legal manufacturer	0.52
10	THE PHOENIX PARTNERSHIP (LEEDS) LTD	Digital health (legal manufacturer)	0.48

Table 7: Top UK companies by GVA/employee

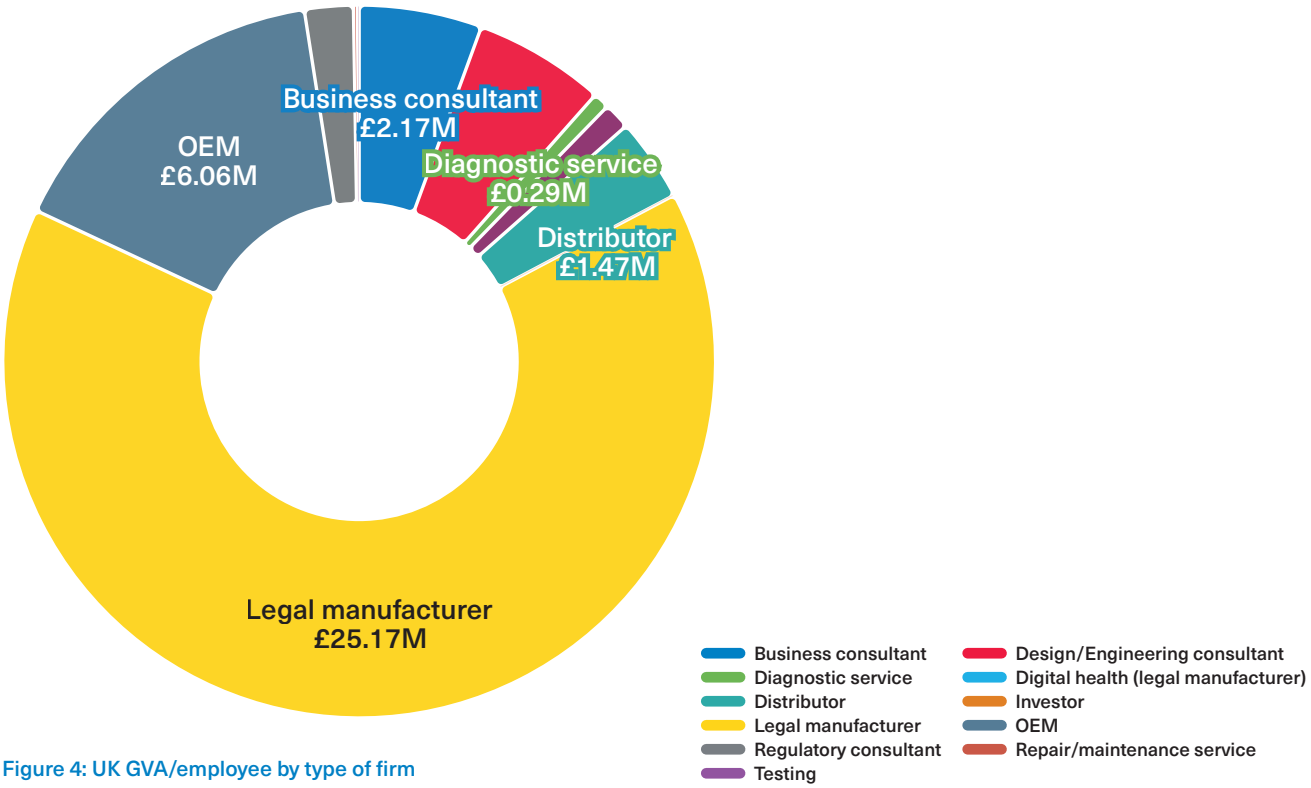

Figure 4: UK GVA/employee by type of firm

Global comparison of GVA per employee

The UK stands in 9th place (our data) or 14th place (UNIDO data) for GVA/employee (Figure 5) and CAGRs vary widely amongst different countries (Table 8). The USA is consistently near the top due to robust funding for R&D compared to the EU and the UK [14].

GVA/employee of the MedTech sector ($k)					
Country	2016	2017	2018	2019	CAGR
Denmark	127	236	245	-	24%
USA	236	218	234	223	-2%
Singapore	192	201	224	294	15%
Switzerland	166	177	190	-	5%
Iceland	159	165	169	-	2%
Belgium	-	109	109	114	2%
Sweden	113	105	120	114	0%
Italy	76	102	108	102	10%
France	90	95	105	93	1%
Norway	114	94	-	-	-6%
Republic of Korea	86	85	-	-	0%
Canada	77	82	77	69	-4%
Netherlands	76	80	85	81	2%
Germany	70	77	91	77	3%
Israel	67	73	68	-	0%
Austria	65	72	74	73	4%
United Kingdom	83	71	78		-2%
Finland	69	71	81	76	3%
United Kingdom	69	65	92	98	12%
Spain	51	52	56	56	3%
Czech Republic	28	29	35	33	6%
Brazil	26	28	25	26	0%
Hungary	30	28	32	36	6%
Croatia	21	24	25	26	7%
Turkey	18	18	18	18	0%
Mexico	14	15	15	17	7%

Table 8: Global comparison of MedTech GVA per employee. Highlighted red value is UNIDO. Highlighted blue value is the Imperial College MedTech database.

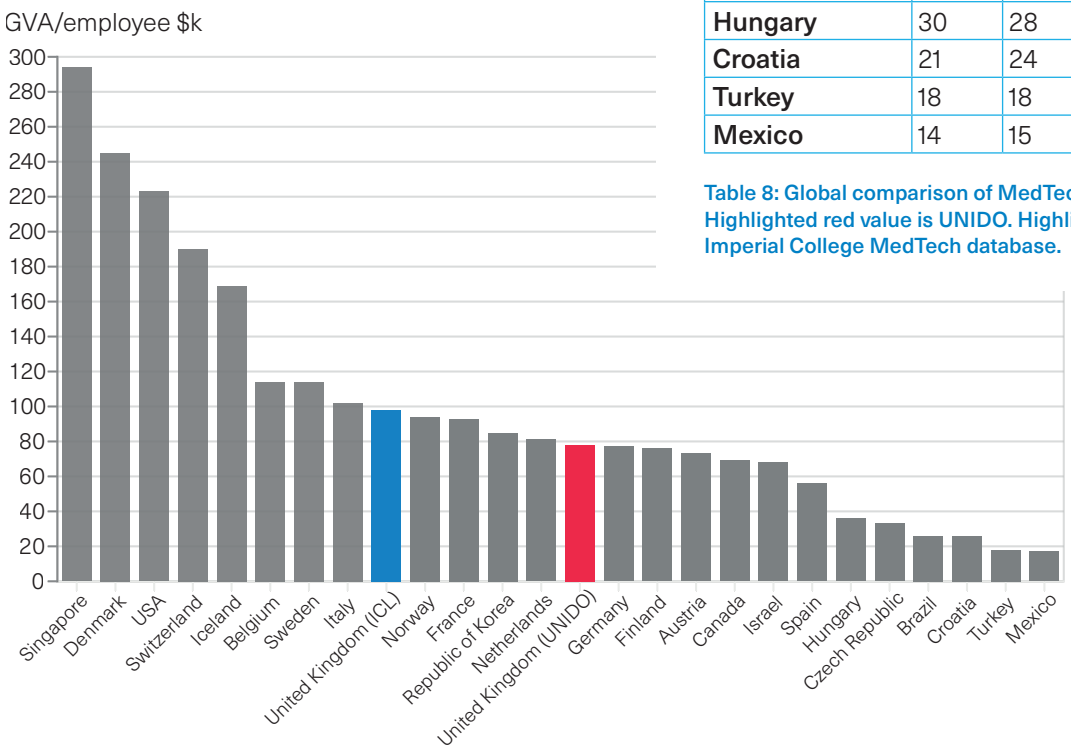

Figure 5: Global comparison of MedTech GVA per employee for 2019 or most recent year available.

Section 4: Analysis of Other Sector Characteristics

UK business counts

Most of the UK MedTech sector is dominated by start-ups, with 950 firms (58%) classified as such (Figure 6). Larger, more established, firms form the second largest cohort. Legal Manufacturers (including Digital Health firms producing regulated technologies) comprise 73% of the sector (Figure 7). The remaining 27% are firms that serve the sector with contract work mainly as consultants and manufacturers (Table 9).

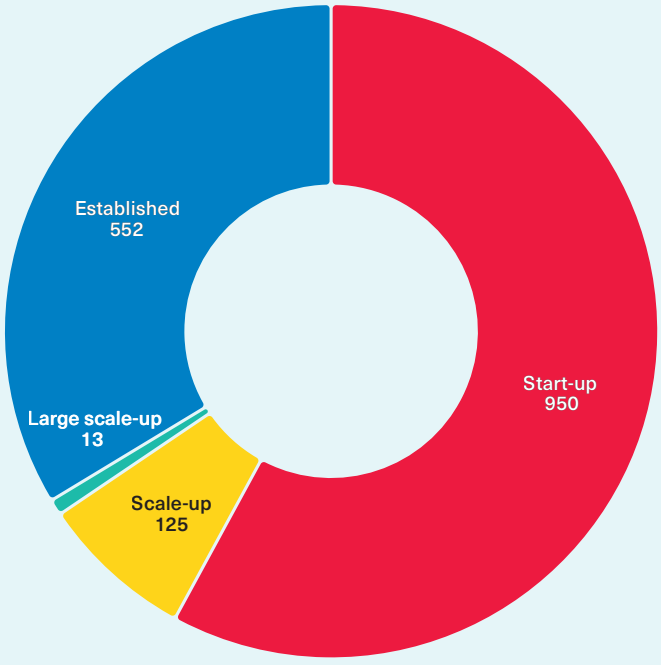

Figure 6: Stage of growth of UK MedTech firms

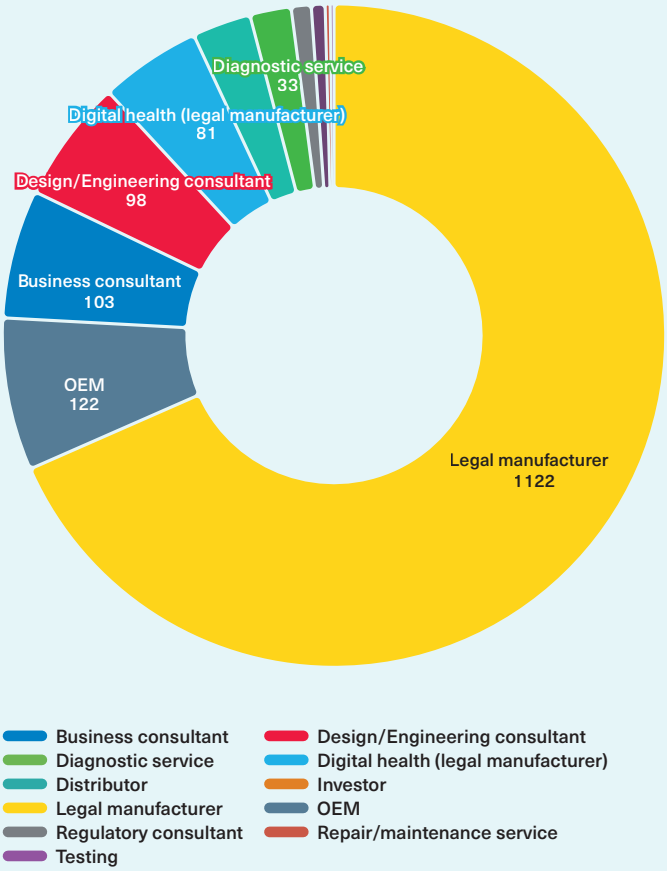

Figure 7: UK MedTech Counts for types of firms

Type of firm	Count
Legal manufacturer	1122
OEM	122
Business consultant	103
Design/Engineering consultant	98
Digital health (legal manufacturer)	81
Distributor	47
Diagnostic service	33
Regulatory consultant	16
Testing	11
Repair/maintenance service	4
Investor	3

Table 9: UK MedTech Counts for types of firms

The total number of firms started to grow quickly in the 1990s (Figure 8). The plateau in 2021-2022 is likely due to the lag in the underlying databases gathering data on newly formed firms. The oldest firms date back to 1902.

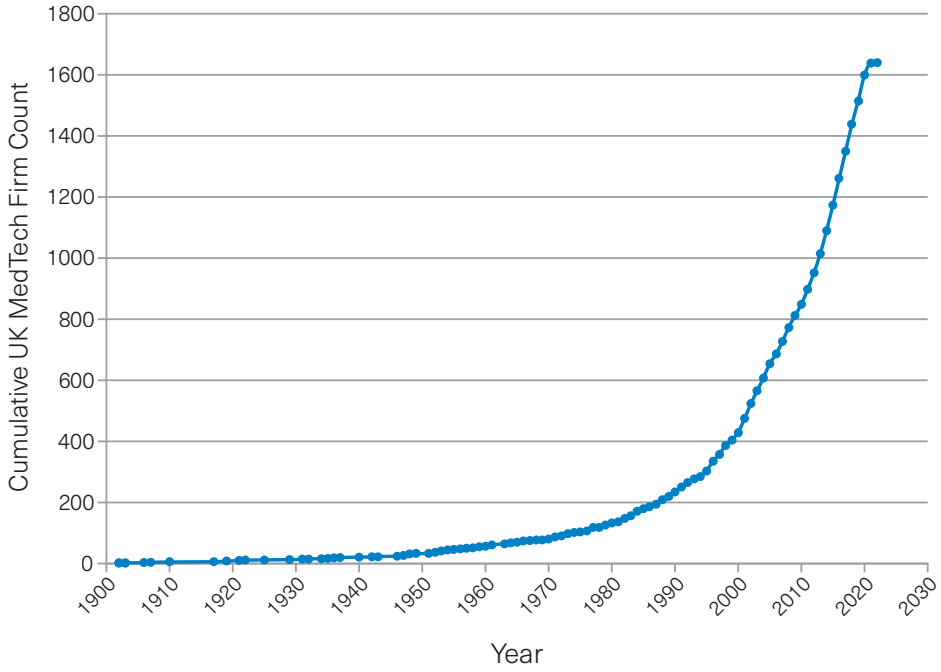

Figure 8: Cumulative growth of MedTech firms

An important source of Legal Manufacturer firms is spinouts from universities. In April 2022 a joint report, commissioned by the Royal Academy of Engineering, was released called Spotlight on Spinouts. Based on the Beauhurst database, they listed the Pharmaceuticals sector at the most common firm classification, with 282 spinouts. However, there are four other categories that comprise MedTech. We used our database to reconstruct their ranking table, eliminating duplicate firms (Figure 9).

The sum of the four MedTech categories was 284 firms, compared to 278 for Pharmaceuticals. These are essentially equal numbers, given fluctuations we observed in the database over the span of a few weeks.

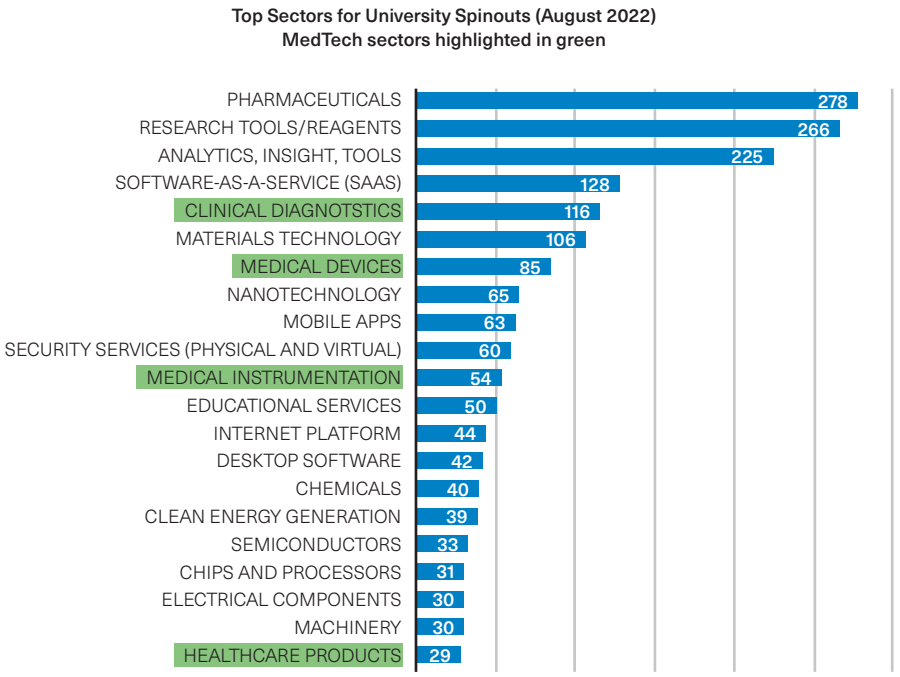

Figure 9: Categorised UK University Spinouts, following the format of the Spotlight on Spinouts report, indicating that the number of MedTech spinouts is roughly equal to the number of pharmaceutical spinouts.

Global comparison of business counts

Relative to its position as the world's sixth largest economy by GDP, the UK houses comparatively few MedTech firms (Figure 10). It appears in 8th position according to OLS data (12th place according to our data) behind countries with smaller MedTech markets such as Italy, Turkey, and the Czech Republic. Germany, Italy, and France provide incentives for many high tech sectors such as export routes due to firms re-investing 9% of their sales back into R&D [15-17].

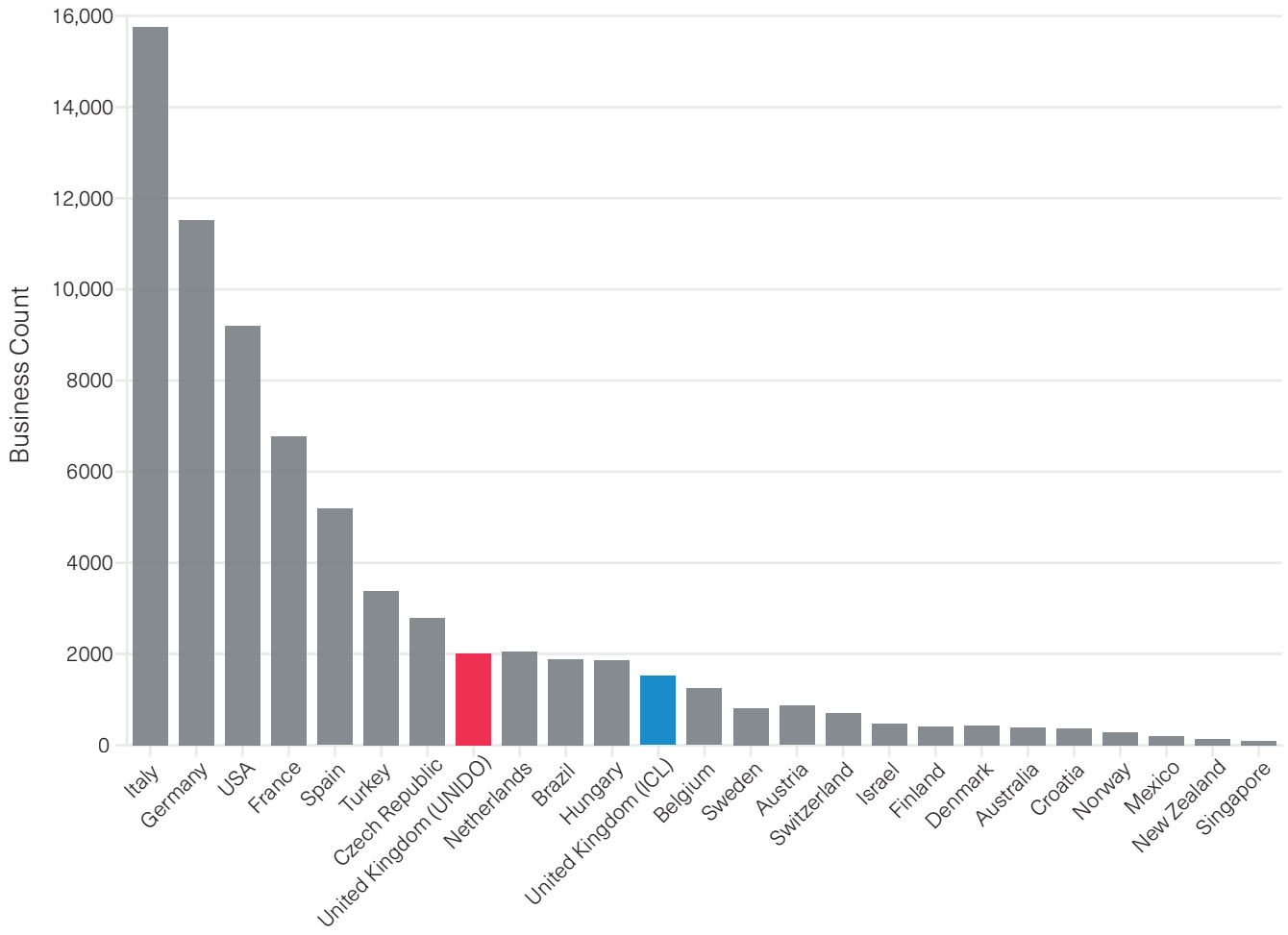

Figure 10: Global comparison of MedTech business count for 2019 or most recent year available.

UK employee counts

The UK MedTech sector employed nearly 163,000 people in 2020, a figure that is growing at 5% CAGR (Table 10). In terms of company size, SMEs dominate the MedTech sector (Figure 6). Fewer than 5% of firms had more than 250 employees. The top 10 firms by employment included five Legal Manufacturers, four consultancies, and one manufacturer (Table 11). Smith & Nephew is the leading Legal Manufacturer in employment with Intertek Group, a consultancy, being the largest employer in the sector. It is worth noting that Intertek services other sectors besides MedTech. Legal Manufacturers employ the largest number of people, followed by Regulatory Consultants (Figure 12).

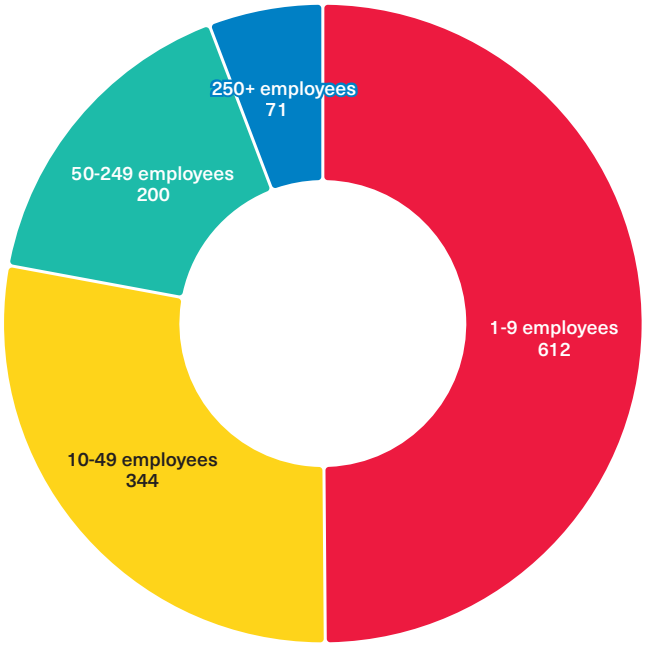

Figure 11: Distribution of employee count in UK MedTech companies

Year	Employee count	
	Total	Number of firms with data
2016	133,809	1139
2017	152,561	1297
2018	160,183	1377
2019	162,622	1449
2020	162,892	1528
CAGR	5%	8%

Table 10: UK MedTech employee count by year

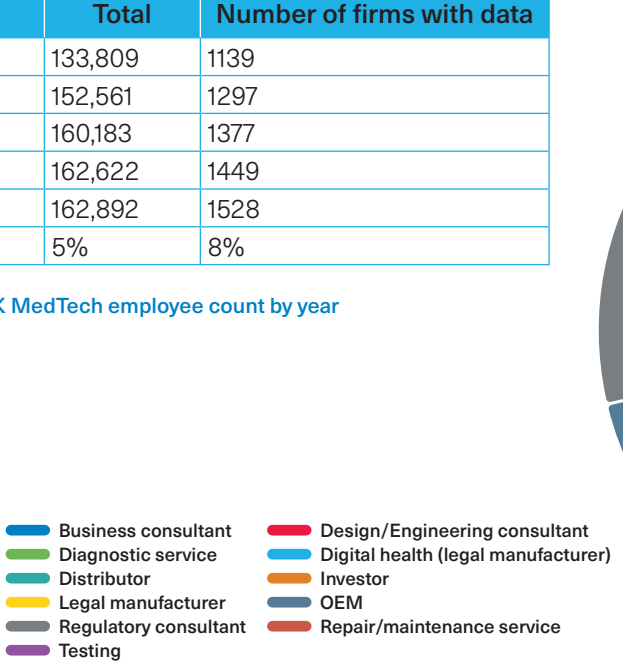

Figure 12: Employee count by type of firm

Position	Top company by employee count (2020)		
	Company	Type of firm	Count
1	INTERTEK GROUP PLC	Regulatory consultant	44,625
2	SMITH & NEPHEW PLC	Legal manufacturer	18,581
3	CONVATEC GROUP PLC	Legal manufacturer	9689
4	TT ELECTRONICS PLC	Design/Engineering consultant	4578
5	RENISHAW P L C	OEM	4437
6	IQVIA LTD.	Business consultant	2834
7	TUNSTALL GROUP HOLDINGS LIMITED	Digital health (legal manufacturer)	2584
8	INHEALTH UK HOLDINGS LIMITED	Legal manufacturer	2507
9	HCL TECHNOLOGIES UK LIMITED	Design/Engineering consultant	2358
10	RANDOX HOLDINGS LIMITED	Legal manufacturer	2112

Table 11: Top UK companies by employee count

Global comparison of employee counts

According to OLS and UNIDO counts, the UK MedTech sector stands in seventh place in terms of employee count (Figure 13). Our database shows much higher numbers, partially due to the accurate inclusion of OEMs and consulting firms. In our database, Legal Manufacturers accounted for 80,000 employees in 2020. However, compared to its closest EU competitors, the UK on average has a slower rate of growth at a CAGR of 3%. Germany and Italy have CAGRs of 9% and 5% respectively. Mexico and Brazil have quite large MedTech work forces, likely due to presence of OEMs.

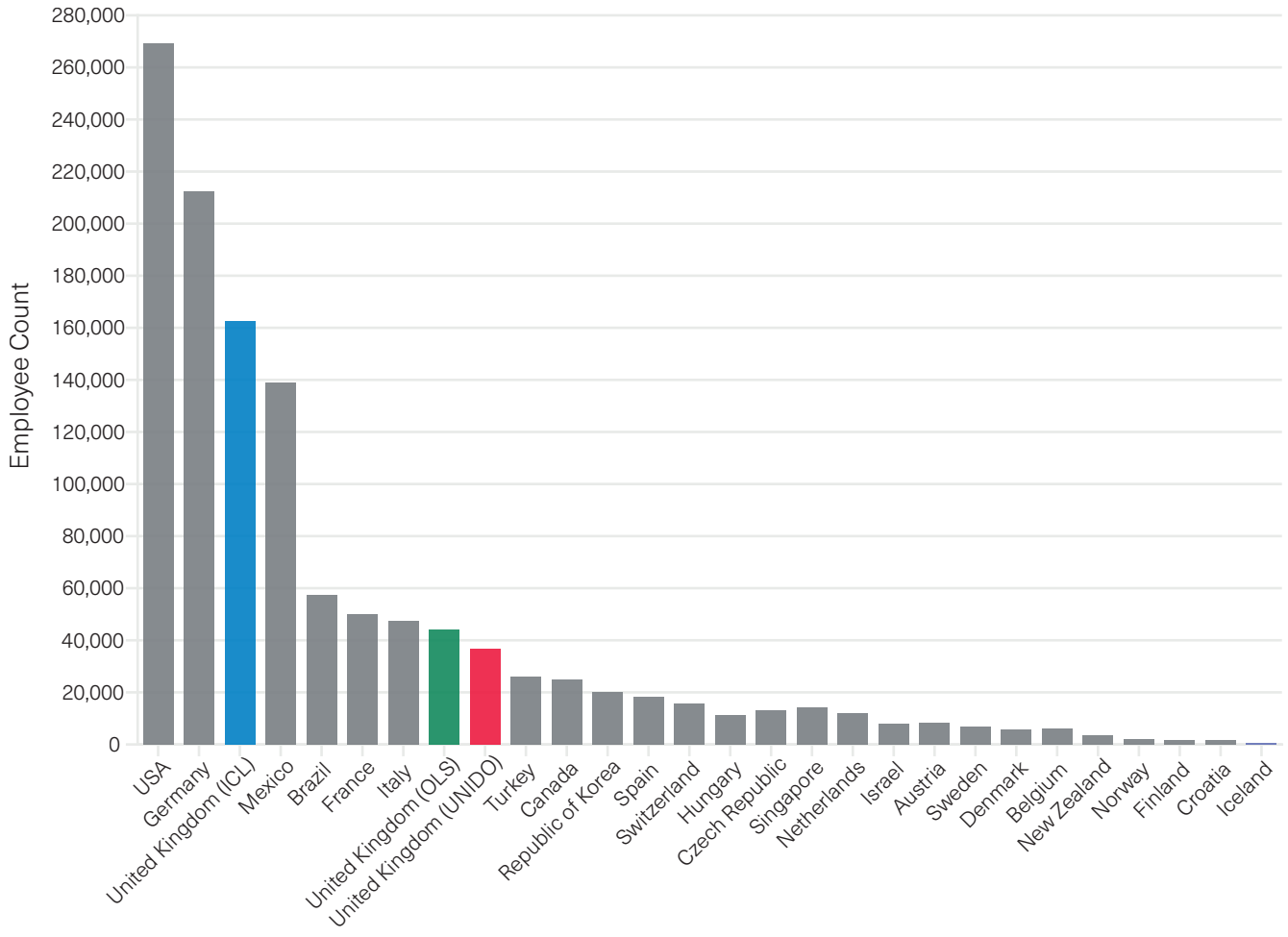

Figure 13: Global comparison of MedTech employee count for 2019 or most recent year available.

UK turnover, wages, and salaries

From 2016-2020, turnover grew by a CAGR of 14%, while wages/salaries grew by 19% (Table 12). The number of total firms in our database increased from 1261 to 1599 (CAGR 6%) during the same period, and firms reporting sufficient financial data increased from 1390 to 1528 (CAGR 8%).

HCL Technologies, a design/engineering consultancy, is the largest firm by both measures, with Smith & Nephew coming second (Tables 13, 14). Although Legal Manufacturers make up half of the top firms by turnover, they are only 2 of the top 10 firms by wages. Consultancies make up most of the top firms by wages. These trends are reflected in turnover and salary numbers sorted by type of firm (Figures 14, 15).

Year	Total turnover (£B)	Total wages and salaries (£B)	Number of firms with data
2016	21	6	1139
2017	25	7	1297
2018	33	10	1377
2019	35	11	1449
2020	36	12	1528
CAGR	14%	19%	8%

Table 12: Turnover and wages data of the UK MedTech sector by year

Position	Top company by turnover (2020)		
	Company	Type of firm	Turnover (£M)
1	HCL TECHNOLOGIES LIMITED	Design/Engineering consultant	7570
2	SMITH & NEPHEW PLC	Legal manufacturer	3495
3	INTERTEK GROUP PLC	Regulatory consultant	2742
4	IQVIA LTD.	Business consultant	1880
5	CONVATEC GROUP PLC	Legal manufacturer	1452
6	HOLOGIC HUB LTD	Legal manufacturer	820
7	RANDOX HOLDINGS LIMITED	Legal manufacturer	619
8	HCL TECHNOLOGIES UK LIMITED	Design/Engineering consultant	594
9	BAXTER HEALTHCARE LIMITED	Legal manufacturer	572
10	RENISHAW P L C	OEM	566

Table 13: Top UK MedTech companies by turnover

Position	Top company by wages and salaries (2020)		
	Company	Type of firm	Wages and salaries (£M)
1	HCL TECHNOLOGIES LIMITED	Design/Engineering consultant	3854
2	SMITH & NEPHEW PLC	Legal manufacturer	1292
3	INTERTEK GROUP PLC	Regulatory consultant	1220
4	CONVATEC GROUP PLC	Legal manufacturer	444
5	L&T TECHNOLOGY SERVICES LIMITED	Design/Engineering consultant	333
6	IQVIA LTD.	Business consultant	252
7	RENISHAW P L C	OEM	224
8	HCL TECHNOLOGIES UK LIMITED	Design/Engineering consultant	187
9	IQVIA IES UK LIMITED	Business consultant	141
10	TT ELECTRONICS PLC	Design/Engineering consultant	130

Table 14: Top UK MedTech companies by wages and salaries

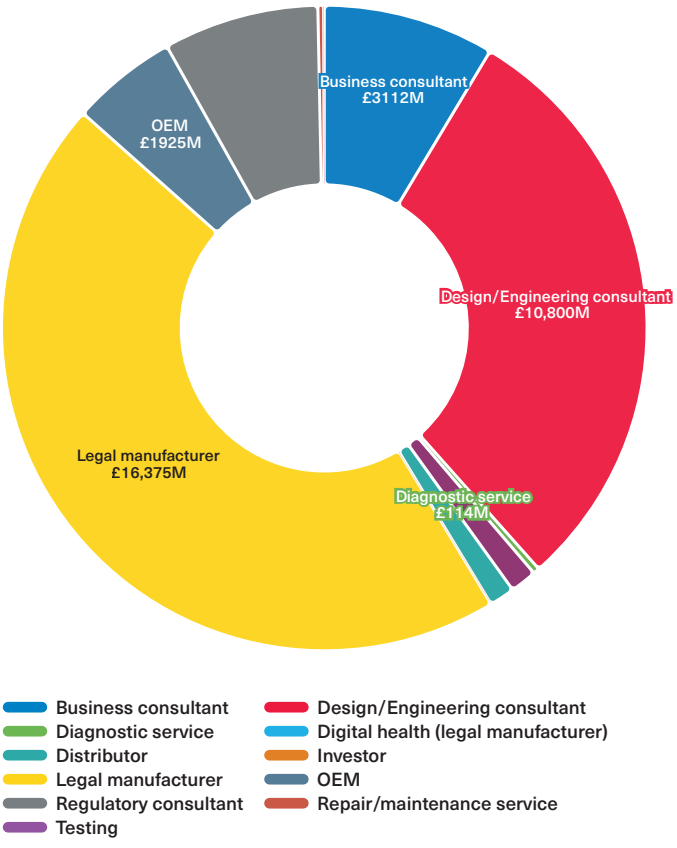

Figure 14: UK MedTech turnover by type of firm

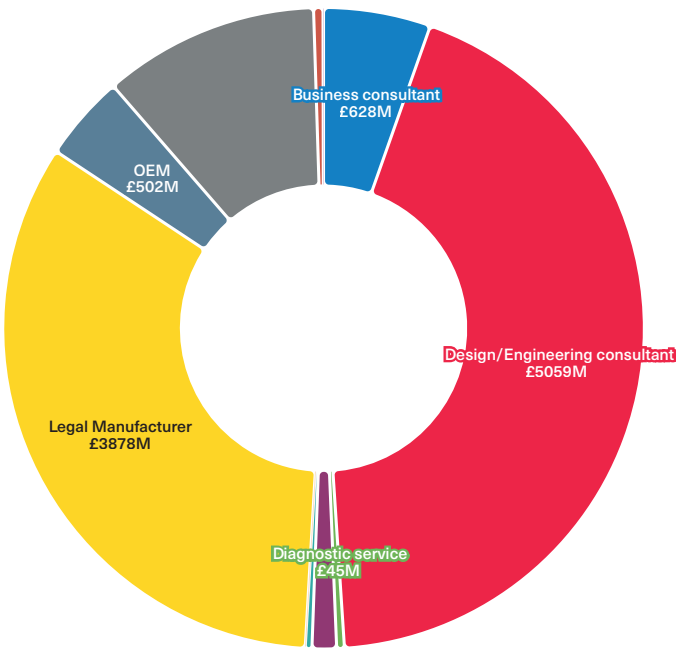

Figure 15: UK MedTech wages and salaries by type of firm

UK MedTech Exports

Following the trend in turnover, exports grew by 16% CAGR from 2016-2020 (Table 15). Consultancy firms accounted for the largest export values closely followed by MedTech firms (Table 16, Figure 16). However, the consulting firm Intertek reported the highest exports by far, skewing these data.

Year	Exports	
	Total (£B)	Number of firms with data
2016	3.25	1139
2017	2.90	1297
2018	3.85	1377
2019	3.78	1449
2020	5.88	1528
CAGR	16%	8%

Table 15: UK MedTech export data by year

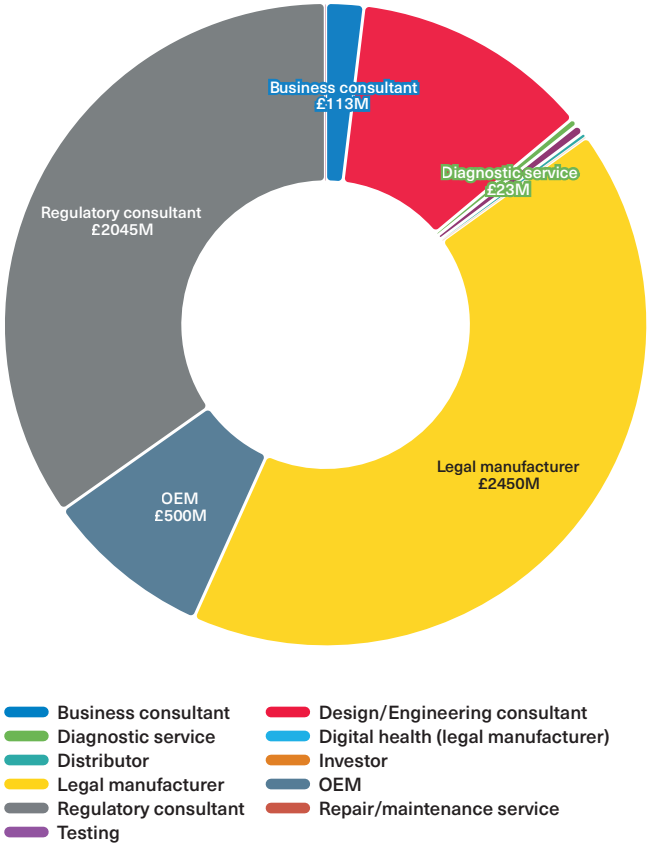

Figure 16: UK MedTech exports by type of firm

Position	Top company by exports (2020)		
	Company	Type of firm	Exports (£M)
1	INTERTEK GROUP PLC	Regulatory consultant	2015
2	ELEKTA LIMITED	Legal manufacturer	325
3	T.J.SMITH AND NEPHEW,LIMITED	Legal manufacturer	310
4	SMITHS MEDICAL INTERNATIONAL LIMITED	Legal manufacturer	225
5	INTERSURGICAL LIMITED	Legal manufacturer	225
6	BECTON, DICKINSON U.K. LIMITED	Legal manufacturer	189
7	LUBRIZOL LIMITED	OEM	180
8	TT ELECTRONICS PLC	Design/Engineering consultant	159
9	HCL TECHNOLOGIES UK LIMITED	Design/Engineering consultant	132
10	SMITH & NEPHEW UK LIMITED	Legal manufacturer	119

Table 16: Top UK companies by exports

Global comparison of export

The UK falls behind many developed companies in its exports of MedTech, with both databases placing it in 10th (our database) and 12th position (OLS) (Figure 17). The USA and Germany lead MedTech exports, followed by Netherlands and China. Singapore has recently emerged as a top exporter, despite a comparatively low number of businesses and employees [18]. These numbers are also influenced by the concentration of distributors in Singapore [19]. One explanation that has been offered for the UK's low MedTech exports is reduced access to the EU as a result of Brexit [20]. Another possible explanation is the dominance of early stage SMEs in the UK that may not have scaled up to having global distribution channels.

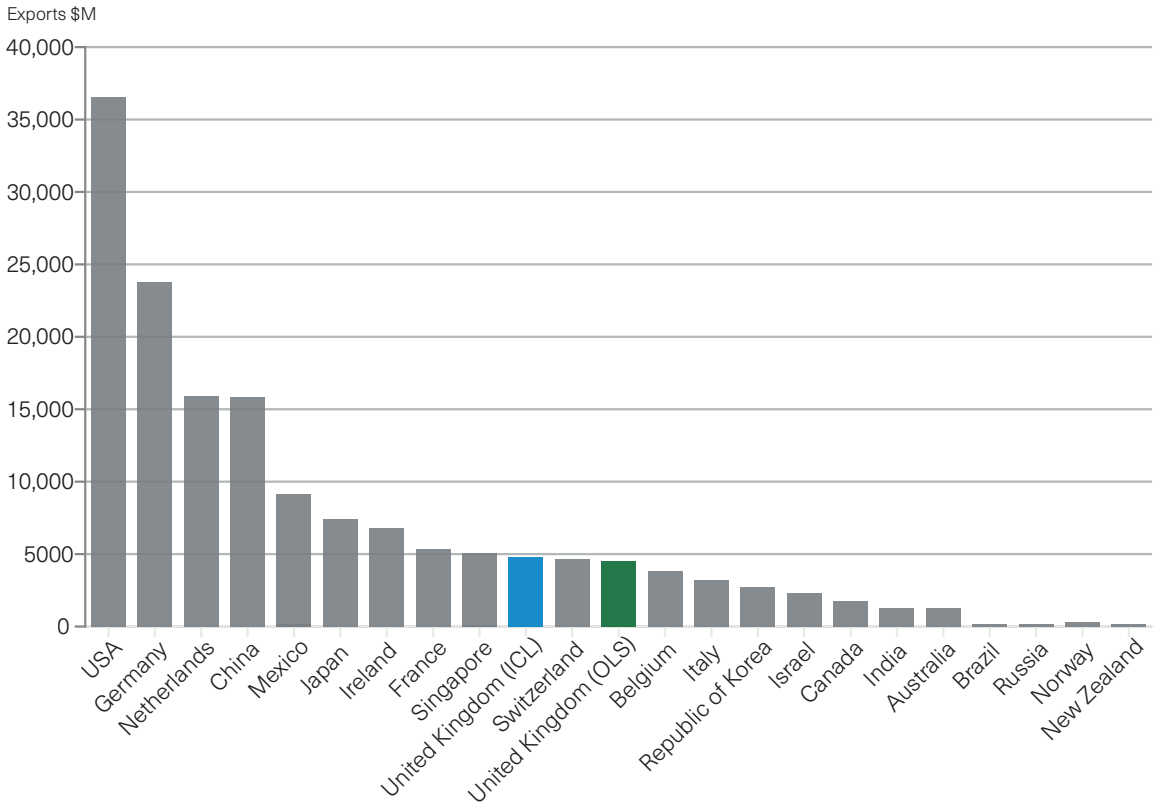

Figure 17: Global comparison of MedTech exports for 2019 or most recent year available.

Global comparison of trade balance

Seven countries with strong numbers of Legal Manufacturers and OEMs lead the rankings of Trade Balance, whereas the UK and the rest of the world show negative balances (Figure 18). The UK's imbalance remained nearly unchanged from 2016-2019 (Table 17).

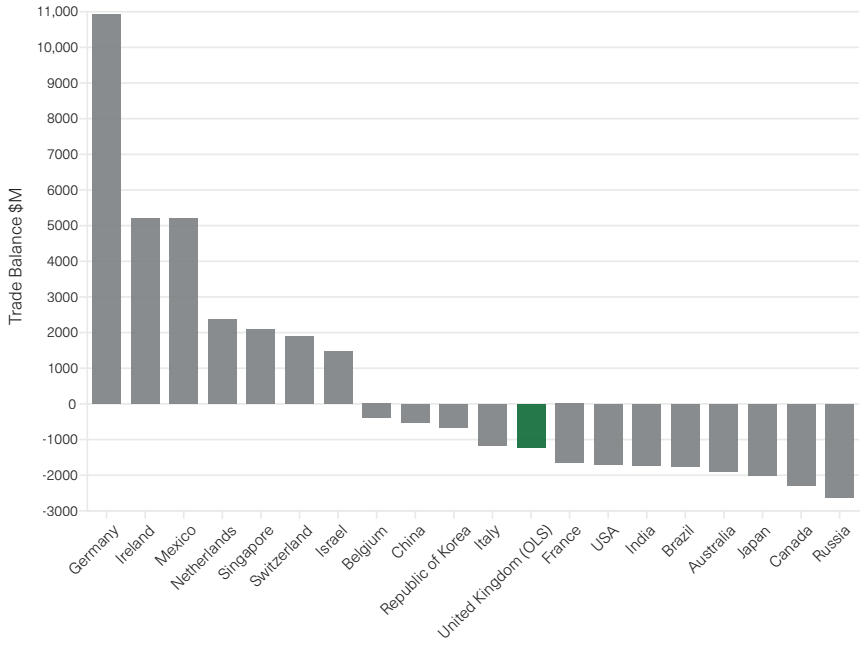

Figure 18: Global comparison of MedTech Trade Balance for 2019. Highlighted green value for UK is from OLS.

Trade balance of the MedTech sector ($M)					
Country	2016	2017	2018	2019	CAGR
Germany	8688	9583	10,419	10,923	8%
Ireland	4274	4255	4730	5215	7%
Mexico	4293	4542	4950	5212	7%
Netherlands	521	1268	2077	2361	65%
Singapore	1136	1588	1561	2083	22%
Switzerland	1392	1720	1991	1889	11%
Israel	1201	1241	1359	1472	7%
Belgium	-59	-21	-363	-395	-88%
China	-262	-349	-885	-525	-26%
Republic of Korea	-377	-461	-540	-660	-20%
Italy	-962	-1148	-1267	-1162	-6%
UK	-1235	-1089	-1140	-1229	0%
France	-1647	-1602	-1324	-1661	0%
USA	2501	1545	672	-1702	-188%
India	-1393	-1630	-1808	-1729	-7%
Brazil	-1343	-1464	-1781	-1752	-9%
Australia	-1726	-1710	-2036	-1895	-3%
Japan	-1491	-1262	-1304	-2009	-10%
Canada	-2149	-2207	-2302	-2281	-2%
Russia	-2060	-2449	-2188	-2633	-9%

Table 17: Global comparison of MedTech Trade Balance. Highlighted green value for UK is from OLS.

UK Regional Data

Business count

The geographical distribution of MedTech firms shows concentrations around larger cities and Higher Education Institutions (HEIs) (Figure 19). MedTech firms were concentrated in 5 regions: Cambridge (76 firms), East central London (76 firms), Oxford (67 firms), Western London (67 firms), and Manchester (55 firms). Other smaller cluster regions include Scotland, Wales, and Northern Ireland. Between the clusters, there are large areas of minimal activity, most notably in the Midlands.

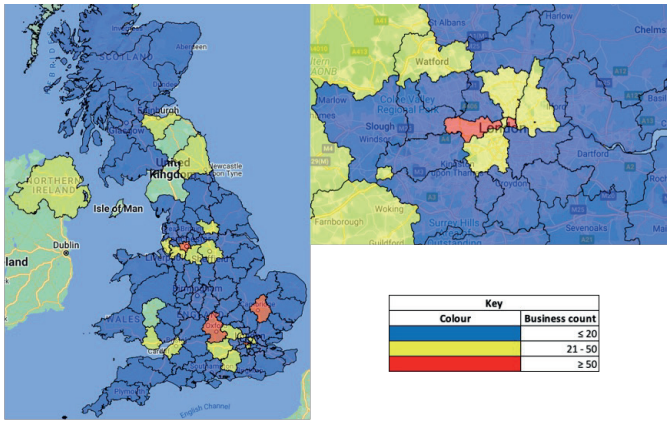

Figure 19: Distribution of MedTech business count by postcode areas across whole of UK (left) and London (right).

Employee count

The presence of large Legal Manufacturer and consulting firms led to employee number concentrations (Figure 20) in Watford (19,604 employees) and Reading (18,787). The Manchester region employee numbers were less than those in the East Midlands and Yorkshire and the Humber.

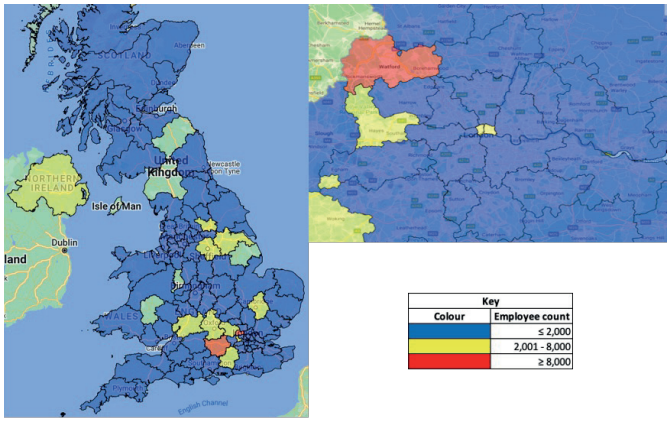

Figure 20: Distribution of MedTech employee count by postcode areas across whole of UK (left) and London (right).

GVA

Four regions exhibited the highest GVA values (Figure 21): Reading (£1.5B), Watford (£1.4B), Northern Ireland (£420M), and Eastern central London (£345M). Northern Ireland showed quite high GVA as well.

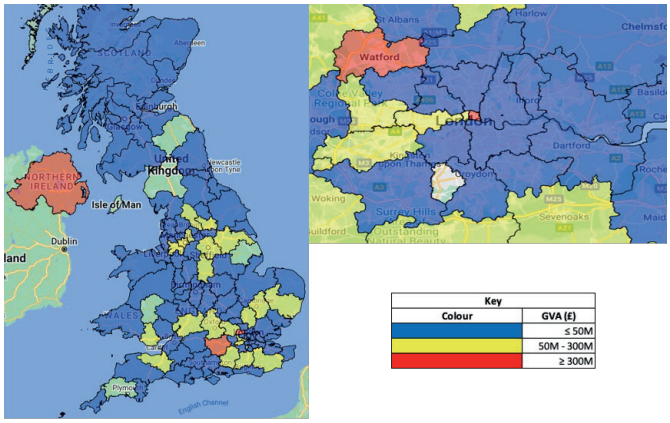

Figure 21: Distribution of sector GVA by postcode areas across whole of UK (left) and London (right).

Section 5: Analysis of UK Sector Funding

Grant funding

Grant funding, as reported by recipient firms (not the funders), grew at CAGR of 23% from 2012-2018 (Table 18). The spike in funding for (fiscal years) 2019 and 2020 was related to the COVID-19 pandemic. Funding in 2021 more or less tracked the preceding growth rate, and 2022 data are incomplete due to lag. The number of firms reporting grant funding grew at CAGR 7% in the 2012-2018 time frame, and 4% overall to 2022.

Innovate UK is the largest grant funder for the MedTech firms in our database, providing 93% of funds awarded 2012-2022 (Table 19). Their awards to the MedTech sector grew at 22% CAGR from 2012-2018 (Table 20). Innovate UK's Biomedical Catalyst program awards approximately £50M per year, but many projects deemed fundable by expert reviewers go unfunded. The shortfall preventing those projects from being funded is approximately £120M per year. Following Innovate UK, the Department for International Development and the Wellcome Trust are the next top funders. The Wellcome Trust funding is related to Pharmaceutical companies that have some device component and thus qualified for inclusion in the MedTech database. The Wellcome Trust typically does not fund purely MedTech development.

Year	Grant funding	
	Total (£M)	Number of firms with data
2022	37	136
2021	64	131
2020	198	287
2019	268	164
2018	59	142
2017	54	154
2016	47	89
2015	37	158
2014	30	115
2013	36	123
2012	17	96
Total	847	-
CAGR	8%	4%

Table 18: Grant funding by year

Top grant funder by amount contributed (since 2003)	
Grant funder by amount contributed	**Amount Contributed (£)**
Innovate UK (IUK)	877,396,467
Department for International Development	16,000,000
Wellcome Trust	7,600,000
Invest Northern Ireland	7,527,393
Small Business Research Initiative (SBRI)	7,301,905
National Institute for Health Research (NIHR)	4,573,136
The Bill & Melinda Gates Foundation	4,410,240
Scottish Enterprise	2,267,173
EIT Health	1,771,241
USA National Cancer Institute	1,675,999
Welsh Government	1,617,832
EIC Transition	1,097,207
Invest NI	1,000,000
Biomedical Catalyst: Development Pathway Funding Scheme (DPFS)	1,000,000

Table 19: Top grant funder by amount contributed

Innovate UK grant funding by year	
Year	Funding Amount (£M)
2022	33
2021	62
2020	182
2019	266
2018	50
2017	51
2016	39
2015	29
2014	29
2013	33
2012	15
Total	787

Table 20: Innovate UK grant funding by year

The National Institute for Health Research (NIHR) provides important MedTech development funding that can go to either companies or HEIs. The amount listed in Table 16 therefore does not encompass their total funding portfolio, which is approximately £20M/ year. In total, the i4i program has awarded over £235M in funding, leading to leveraged funding of £940M into MedTech startups, 115 products achieving CE mark, and 2 IPOs raising £190M.

Submissions to the i4i PDA program have risen from 81 in 2018/2019 to 132 in 2021/2022 (Figure 22). Success rates from original submission through the two-stage review process have dropped from 17% to 11% in that same time frame. NIHR is scheduled to receive a 30% increase in its funding for the 2024-2025 fiscal year.

NIHR also manages the Small Business Research Initiative (SBRI) funding scheme, which issues a few calls each year targeted at meeting specific NHS needs. They typically award up to £20M per year, with success rates running at approximately 10%.

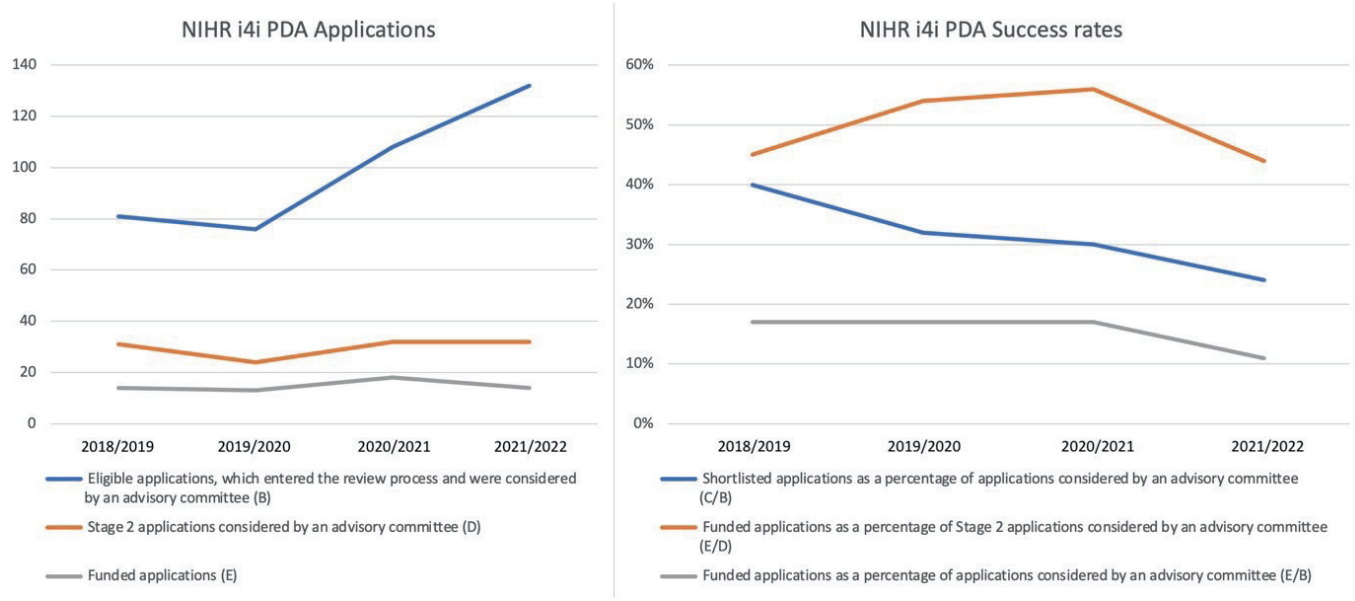

Figure 22: Submission numbers and success rates for NIHR i4i PDA program

Investment funding

Self-reported funding to UK MedTech firms fluctuated from approximately £100M/year to over £1B/year (Table 21). These fluctuations are due to a few sporadic large deals, mainly by Syncona Partners. Overall, investment funding contributed 12 times more funding to the sector than grant funding from 2012-2022.

Syncona invested more than 2X the next highest firms (Table 22). This is tied directly to 5 investment rounds in Cambridge Epigenetix, Blue Earth Diagnostics, and Gyroscope Therapeutics. Two of these firms are mostly biopharmaceutical (which is Syncona's focus) but were captured in our database due to companion diagnostic products.

Year	Investment Amount (£M)	Investment Rounds
2022	167	56
2021	5409	131
2020	303	114
2019	1080	88
2018	379	115
2017	211	103
2016	239	95
2015	148	79
2014	166	55
2013	1101	32
2012	25	31
Total	9,228	899

Table 21: Investment funding by year

Investor	Investment Amount (£M)
Syncona Partners	110
Undisclosed investors	49
Business Angel(s)	35
Sanofi	29
Touchstone Innovations	25
Tikehau Capital	23
BGF Growth Capital	18
Archangels	18
Foresight VCT	15
TELUS Ventures	15
Vita Spring	15
Wealth Club	14
Parkwalk Opportunities EIS Fund	14
Apposite Capital	12
Mercia Fund Managers	11
Lundbeckfonden Ventures	11
Seedrs	11
MMC Ventures	10
Crowdcube	10
Cambridge Angels	10
SyndicateRoom	9
British Patient Capital	9
Growth Finance	8
NPIF Equity Finance	7
Boehringer Ingelheim Venture Fund	7
Connection Capital	7
Par Equity	7
Avingtrans	6
IP Group	6
Beringea	6
Mercia EIS Fund (Growth Fund)	5
Scottish National Investment Bank (SNIB)	5
Business Loan	5
Caple	5

Table 22: MedTech Professional Investments 2012-2022

Section 6: Stakeholder Interviews

Apart from education, all discussed topics elicited negative overall responses, indicating the variety of challenges to the sector (Table 23). We anecdotally observed a shift in focus during 2022 from regulations being the main concern to funding and NHS procurement. The funding concerns are likely related to the global 35% decline in VC investment from 2021 [21].

Other economic issues included shortages of grant and investor funding in the sector. Respondents said there was not enough grant funding for the sector, and that application processes were excessively complex. Some expressed concerns that most grant funding went to firms in the South East.

There was an overall positive view of the UK educational systems in terms of supplying a high-quality workforce, with respondents saying, "The academic sector is very strong," and, "Thriving pool of skills available in the UK." However, even respondents with a positive impression of UK education commented that universities make it too difficult to translate the fruits of research into innovative products. A consortium of UK University Technology Transfer Offices and VC investors has provided a guidebook intended to facilitate technology licensing into university spin-outs (The USIT Guide Launch: Event Highlights).

	Regulation	Funding	NHS procurement	Startup support	Education	Manufacturing	Innovation translation
Positive opinions	1	2	0	2	20	2	2
Negative opinions	37	28	42	23	0	15	27

Table 23: Results from the stakeholder analyses

Of the 15 Legal Manufacturers interviewed, the main three concerns were NHS procurement, regulations and funding, in decreasing order. Respondent quotes included, "The NHS is not great at adopting technology," "The NHS procurement process is terrible and doesn't favour SMEs," and "The NHS doesn't have enough funds to purchase risky innovative technology." These concerns were echoed by MedTech trade groups, with one representative stating, "The capacity for innovation, research, and development is large in the UK [but] it is difficult to convert research into marketable devices and create medical technology firms. Much more difficult here compared to other countries." VCs cited the concern that, "Clinical trials are now being carried out more and more in the USA, and the USA is being seen as a more viable market now."

Regulatory barriers

The topic that elicited the most negative comments was the uncertainty in the UK regulatory environment. As summarised in Section 1.3, the UK decided to depart from alignment with EU regulatory practices after Brexit. This has presented serious challenges for Legal Manufacturers who are targeting the NHS as an early adopter. The transition to UKCA means that all devices currently used in the NHS will have to be re-certified. While the deadline for re-certification has been pushed back to 2025 or beyond, this requires a massive effort by Legal Manufacturers of all sizes and firms that support them in pursuing regulatory approval such as consultants and Notified Bodies (now called *Approved Bodies* in the UK). There are therefore few resources available to bring new devices into the UK market.

Respondents showed great concern for the overloading of Notified Bodies, stating "Notified bodies have limited resources due to the changing regulations" and that they are "limiting the number of firms they are working with". These findings complement previously published reports on the sector [22, 23].

Procurement barriers

Procurement was also identified as a large barrier to the sector, often being referred to as the main cause for Legal Manufacturers avoiding the UK market. Several respondents provided comments such as, "The NHS procurement is very risk-proof, which makes it difficult to enter. It needs to be more agile." There are also complaints that receiving support from Academic Health Science Networks (AHSNs) has no influence on NHS procurement, even though that is one of their intended roles.

One observation shared by many respondents was that in response to COVID-19, both regulations and NHS procurement were adopted to assist with pandemic response. Some respondents called for those changes to be permanent, saying, "During COVID-19, the adoption time of innovative technology (vaccines) was impressive. This should continue into the general medical technology sector as it is proven to be possible." This is tempered by the reality that organisations involved in approving those devices dedicated such a large effort to that focused task. Then, in 2021, the MHRA reduced its staff due to budget cuts [24]. The resulting lack of bandwidth will likely impede the progression of UK-based technologies and incentivise the pursuit of better resourced markets such as the USA.

Case Study in Poor Adoption of New Technology by NHS: Forte Medical

Forte Medical makes a unique midstream urine collection (MSU) device, shown to deliver significant cost savings, improved patient care and reduced antibiotic prescribing in real-world trials.

Barriers to adoption within the NHS means the device has been withdrawn from the UK market, despite selling into the USA with Medicaid HCPCS (reimbursement code) refunding the physician USA$48-$63 for women's health.

Impediments to NHS adoption, according to Forte Medical

- Siloed budgets: disconnect between funding prevention compared to funding for cures;
- Apathy, inertia and resistance to change at ground level, even with clear evidence showing superior performance of MSU device;
- No incentive for labs to improve first-time outcomes as they are paid per specimen;
- Poor specimen collection is most common cause for over-prescribing antibiotics but guidelines for Anti-microbial resistance stewardship are not being applied.

Suggested solutions based on Forte Medical's experience

- Remove vested interests of key parties and chain of command in maintaining status quo;
- Provide short training courses to ward staff to demonstrate benefits of adopting improved methods;
- Create a protocol for urine collection, giving it parity with blood diagnostics;
- Invest in Primary Care diagnostics with precision methodology;
- Train procurement executives in the cost and clinical value of superior technology even when that solution has greater upfront investment;
- Better communications between innovators, procurement and finance;
- Enact reasonable and required price rises on the NHS Supply Chain;
- Appoint a named innovation lead in each Trust;

Refer to Appendix 2 for further information.

Section 7: Conclusion and Recommendations

Highlights from database

The UK MedTech sector shows many positive characteristics that indicate opportunities for economic growth, high quality employment and healthcare impact. Important traits include:

- The sector is primarily composed of SME startups looking to grow.
- Current growth is robust, with 2016-2020 CAGRs in turnover at 14%, wages at 19%, exports at 16%, and GVA at 19%. These growth rates exceed the growth in number of firms reporting data (5-8%).
- GVA/employee is growing at 13% CAGR and is now approximately £100k. By comparison, GVA/employee for the UK Biopharmaceutical sector stands at approximately £170k.
- The sector is heavily reliant on grant funding and professional investment due to the time and resources required to achieve regulatory approval for marketing.
- The UK sector has a good international profile, but the "spacing" from the worldwide leaders indicates opportunities for growth. For example, MedTech GVA/employee is over $150k in five other countries.

The pipeline of university spinouts is an important foundation for the UK MedTech sector. There are more MedTech spinouts than any other type of university spinout; roughly even with biopharmaceuticals. These are largely Legal Manufacturers based on potentially impactful intellectual property. The underlying annual research funding basis for MedTech (EPSRC Healthcare Technologies and NIHR, 2020-2021 data) stands at approximately £140M/year. This is approximately 6% of the funding basis for Biopharmaceuticals (BBSRC, MRC, Wellcome Trust, British Heart Foundation, Cancer Research UK), which totals over £2B per year. The UK could become a world-leading producer of innovative MedTech products with comparable underlying support.

While Legal Manufacturers are prime drivers of the sector by virtue of their intellectual property portfolios, there are important contributions from firms that support them. The capital requirements required to establish and maintain regulatory-compliant design and manufacturing infrastructures leads most Legal Manufacturers to rely on consultancies and OEMs. It is therefore reasonable to include these other firms in the sector assessment.

Limitations of our database:

- Data availability is an issue, especially for smaller MedTech firms and investment transactions that are confidential or were not reported by the underlying databases on which ours was built.
- Our database is composed of firms that produce devices requiring regulatory approval, and thus excludes some HealthTech firms that produce consumer products that do not claim medical benefit. This exclusion was intended to focus our analysis on high value-added products with intellectual property protection and regulatory approval documentation. However, by definition this underestimates the size of the HealthTech market that would include many other beneficial and potentially high value-added technologies. Expanding this sector analysis to include such firms would be a worthy activity.
- We have not included sales subsidiaries of multinationals who market MedTech products in the UK. While the economic impact of these businesses is not insignificant, they typically would not own the underlying intellectual property or be responsible for manufacturing.
- We manually filtered our database, which limits comparability to other databases which have not been so stringently filtered. Our initial enquiries into the OLS, DataCity and Beauhurst databases yielded 744, 1574 and 1238 firms, respectively (combined 3556). Our final database has 1640 firms after removing duplicates, firms that were not really MedTech, and other outliers.

The UK MedTech regulatory environment

As of this writing, the uncertainties concerning the MHRA are the most worrying issues to stakeholders in the MedTech sector. There are multiple negative aspects and multiple reasons for concern. Surrounding this uncertainty is the difficult transition in the EU from MDD to MDR. Access to this very large market for all MedTech firms will be potentially compromised by the higher level of scrutiny and the need to comply with MDR. Some 70% of devices currently on the market are non-compliant as of this writing, so Notified Bodies are swamped with requests for reviews.

In that context, the MHRA initially announced it would maintain most aspects of MDD in setting up the UKCA. However, that process has proved problematic because the UK represents only 3% of the worldwide MedTech market, and would be the only country still using MDD. Because that could lead to MedTech companies abandoning the UK market, the MHRA has since struggled to establish a functional way forward. A consultation in late 2021 yielded clear signs of industrial dissatisfaction but has yet to lead to a plan

that has completely settled concerns. In April 2023, an open letter to the Prime Minister, coordinated by the British Healthcare Trades Association, outlined continuing serious concerns about uncertainty in the MHRA's processes [25]. Furthermore, the reduction in workforce at MHRA has had serious implications on their MedTech expertise.

These uncertainties have hindered progress for UK MedTech firms who would otherwise like to sell into the UK market. Given the further uncertainty in the EU, many UK firms are solely targeting the USA market, the largest market in the world which also features a known, stable regulatory system. The constant quest for grant and/or investor funding is made much more complex by these factors. Time will tell if targeting the USA market leads to MedTech companies moving all operations there, but there are many who say that is already happening.

This transitional period for the MHRA also provides opportunities to establish a regulatory environment that would encourage testing and adoption of new technologies. For example, with appropriate resourcing, the MHRA could emerge as a world leader in the adoption of cost-saving regulatory practices such as in-silico evidence of device performance [26]. Industry engagement is crucial in designing functional mechanisms to achieve these goals.

Recommendations - regulatory:

Recommendation One: The MHRA should clarify its plans to accept devices approved in larger markets such as the USA and EU.

Recommendation Two: The MHRA should coordinate with industry to develop mechanisms to encourage MedTech companies to perform clinical trials in the UK, perhaps directed at under-recognised diseases. Since 2019, the UK has fallen behind in the number of clinical trials being carried out [27].

Recommendation Three: HM Treasury should immediately increase the MHRA's budget so that its staff can be available to interact with Legal Manufacturers about their prospective applications, process applications and provide appropriate post-market surveillance.

Recommendation Four: MHRA and other market-shaping regulatory and investment bodies should establish incentives for UK Approved Bodies to grow in number and size to support the transition to UKCA, including incentives for training programs in regulatory affairs in the higher education sector.

Recommendation Five: MHRA must address these issues with the appropriate urgency, recognising that the NHS may soon lose access to the medical technologies it requires to function.

UK MedTech sector funding

This was the next most concerning issue for MedTech firms in the UK, particularly beginning in early 2022 when global events led to a 35% decline in venture funding. In parallel, translational funding from the EU has been endangered by Brexit. Applications for grant funding for MedTech have increased in number, leading to success rates of around 10% or less at NIHR (for early-stage projects perhaps still within universities) and Innovate UK (after company formation and partial funding). Both programs fail to fund many proposals that reviewers have deemed worthy of funding. These grants not only provide crucial operating capital, but also signal validity to investors and enhance odds of follow-on investment.

Recommendations – funding:

Recommendation Six: The Department for Health and Social Care and UKRI should increase funding levels for NIHR, and Innovate UK programs, respectively, that support MedTech development to provide for success rates of at least 20%, or such that 90% of fundable projects can be funded.

Recommendation Seven: UKRI should establish a new stream of MRC DPFS aimed at MedTech, allocating a budget that at least aligns with NHS spending on medical devices (approximately half that of biopharmaceuticals). This would provide an additional source of funding for early-stage technologies and help fill a void created by the fact that NIHR is not allowed to fund preclinical in vivo testing.

Recommendation Eight: Funding bodies should streamline and simplify application processes.

Recommendation Nine: HMRC must continue the SEIS/EIS programs, growing in size to account for inflation.

Recommendation Ten: HMRC should restore R&D Tax Credits to at least previous levels, and improve targeting of SMEs for these benefits.

Addressing uptake and procurement of new technologies by the NHS

The NHS requires a drastic overhaul in its innovation and procurement culture. Currently, it is not effectively exploiting the large amount of innovation from the UK MedTech sector. Many of our survey respondents stated that the current procurement system actively discourages purchasing of innovative devices despite proven benefits such as long-term cost-savings.

The economic benefits of a robust UK MedTech sector will continue to be diminished if Legal Manufacturers struggle to enlist a customer base locally as they approach the regulatory approval and marketing stage.

These faults in NHS adoption of new technologies were not intended as a primary topic of this report. Given their prevalence in stakeholder input, a deeper study of these issues, including case studies of successful local networks (e.g., Health Tech Enterprise) should be performed. The brief list of recommendations below reflects the input we received.

Recommendations – NHS

Recommendation Eleven: NHS procurement teams should communicate actively with MedTech suppliers about the technology they most require and develop more industry-friendly procurement approaches.

Recommendation Twelve: Establish and fund programs that target early-stage clinician engagement with UK-based MedTech companies at both NHS Trust and national (Department for Health and Social Care) levels. This will increase likelihood of eventual NHS-wide uptake. Funding should provide resources for clinician engagement at all care levels and include nurses. Health Tech Enterprise provides a good example of an organisation that encourages local engagement with MedTech SMEs.

Recommendation Thirteen: The Department for Health and Social Care, and individual NHS Trusts, should develop and provide new resources for further innovation and entrepreneurial activities within the NHS. This could include expansion of the NHS Clinical Entrepreneur Program and dedicated technology development managers with whom NHS staff could approach for addressing unmet needs at all care levels.

Education for UK MedTech sector

The UK MedTech stakeholders generally had a very positive view of HEI's provision for its workforce. While this should be viewed as a strength worthy of continued support, there is also an opportunity to leverage this educational excellence to address the issues raised above. Expanding the capabilities of MHRA and Approved Bodies will require educational programs in regulatory affairs. Currently, these organisations rely on a combination of a technical background and relevant experience to supply their workforce. This is not conducive to the rapid growth necessary to support the UK MedTech sector.

The research and development efforts within HEIs also create a robust environment for MedTech device invention and spinout formation. Yet, these companies struggle to build momentum and attract investment. This is in part due to antiquated technology transfer practices in HEIs. Many UK universities still have policies that seek a 50% equity stake in spinouts, whereas the most successful universities abroad have moved to a 5% stake to make their spinouts more attractive for downstream funding. UK companies compete in a global environment for investment funding, and investors do not like companies whose capitalisation tables are loaded down with passive equity holders. While the TenU consortium report should be useful for explaining the parameters of technology transfer negotiations, they still recommend a 10-25% university equity share.

Recommendations – education:

Recommendation Fourteen: Both the MHRA, and individual HEIs, must encourage the growth of engineering and science courses that integrate regulatory affairs and relevant internships directly into curriculum and practice.

Recommendation Fifteen: HEIs must adapt "low friction" policies for technology transfer in which control remains in the hands of those whose efforts will be required for success. University equity stakes greater than 5% will make UK spinouts less attractive for funding than international competitors.

Glossary

Term	Definition
CAGR	Compound Annual Growth Rate
CE Mark	*Conformité Européenne* indication of compliance with EU standards
GDP	Gross Domestic Product
GVA	Gross Value Added
HealthTech	Technologies that provide health-related information to consumers, clinicians and patients to assist in maintaining health, improving health, or treat diseases (encompasses MedTech). Not all products in this category would require regulatory approval for marketing.
ISO	International Standards Organisation
Legal Manufacturer	Firm recognised by governmental regulators as assuming legal liability for marketing a medical device
MDD	Medical Device Directives, the EU system for MedTech regulation scheduled to be phased out in 2024
MDR	Medical Device Regulations, the EU system for MedTech regulation scheduled to be fully implemented in 2024
MedTech	Technologies that make claims of medical benefit and this require regulatory approval (our definition)
MHRA	Medicines and Healthcare products Regulatory Agency, the UK's regulatory agency (Competent Authority)
NHS	National Health Service
Notified Bodies/Approved Bodies	Firms licenced by governments to audit and provide assurance for conformance to relevant standards. The UK switched to the term "Approved Bodies" after Brexit.
ONS	Office of National Statistics (UK)
OEM	Original Equipment Manufacturer, in this context a firm contracted by a Legal Manufacturer to produce a device
QMS	Quality Management System
SIC codes	Standard Industrial Classification codes
UKCA	UK Conformity Assessed, the post-Brexit replacement for CE Mark

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Appendix 1:
Interview Structure

- What does the UK do well and not so well in terms of the MedTech sector?
- What are the main challenges or barriers facing MedTech firms or the firms which serve them?
- [Specific question relating to type of firm]
- Can you provide a comparison of the UK's MedTech sector to another region's sector regarding your area of expertise?
- What changes would you like to see to make the sector more accommodating?

Appendix 2:
Additional information on NHS failure to adopt Peezy device by Forte Medical

Innovation adoption in the NHS: a case study
Barriers, flawed systems, silo budgets … and vested interests

Author: Giovanna Forte
May 2023

-30mm-

GP to female patient: *Put your urine sample in here please and try and collect midstream so we can get a good look at what's in there. The best method is to start to pee, stop, put the tube underneath you and start again.*

(Ten minutes later)

Female patient: *I can't believe you gave me this, Doctor. It was almost impossible and messy, my hands were soaking, so was the loo … and the label's so wet you can't write my details on it.*

In 2002 this conversation took place in the surgery of Dr Vincent Forte BA (Cantab), MBBS (Lond), MRCGP, MSc, DA.
Vincent was used to this; almost all female patients made the same complaint. He wondered if this issue led to the many repeat visits he had from patients whom he *thought* he had treated by following guidelines, but who seem not to have responded to the recommended broad-spectrum antibiotics? Vincent called his sister, a businesswoman:

V: *All these women complain about giving their urine sample into a tiny tube. Most of them have to come back for retesting for some reason. There must be a better way. What should I do?*
G: *Make something. You were always making things when we were small. That should solve the problem.*

What are the problems that Vincent identified?

- Global guidance specifies midstream urine (MSU) for Urinary Tract Infections (UTI) and prenatal screening, yet there is no protocol or device available to ensure guidelines are met (unlike for blood, urine's diagnostic counterpart);
- Current start-stop-start collection method cannot guarantee midstream and is difficult if pregnant;
- First-void urine can wash flora and bacteria from the skin into the sample, creating contamination;
- Contaminated specimen is harder to analyse due to creation of "mixed growth" bacteria;
- Unreliable specimens lead to high volumes of retesting and false-positive results;
- Repeat testing at frontline is costly (HCP time to recall patients followed by clinician and lab time);
- Unreliable specimens leads to unnecessary prescribing (poor AMR stewardship);
- Untreated UTI leads to chronic conditions, kidney disease and unplanned hospital admissions;
- Hygiene: soiled patient hands can spread pathogenic bacteria and viruses found in urine and on the perineum into the environment (toilet flush, door handles, taps). The list of microorganisms is long but can include E-coli, Streptococcus, Staphylococcus, Proteus, Enterococcus, Gonorrhoea, Chlamydia, Hepatitis B, HIV, and more

FURTHERMORE (the interesting bit)
Laboratories are paid *per specimen* by the NHS, removing any incentive to improve urine collection, reduce retests and false-positives. Urine is the most common specimen delivered to labs across the UK and its unreliability for routine diagnosis seriously impacts women's health and leads to chronic conditions, over prescribing of antibiotics and more. Are women now on the frontline of AMR? Payment contracts MUST be overhauled to ensure taxpayers money is delivering benefit to the patient. In 2012, we were told by a leading private lab working for the NHS that *Peezy Midstream would remove around £500,000 from our bottom line.* Discussing this in 2018 with the then Chairman of the NHS, he responded: ***The private companies we commission have to make money or they wouldn't do the job.***

NB UCLH, the Royal Free and TDL now have a joint venture business with both NHS Trusts sharing profit. Arguably, close analysis of lost savings opportunity may point to greater savings than profit reaching the Trusts if a specimen analysis compensation was based on quality, accuracy and a reward for savings delivered to the NHS.

Urine Specimens	National Average
Number taken annually UK	65,000,000
Number taken every working day	259,000
Percentage of unreliable specimens	22.5%
Patients failed by routine and specialised urine analysis, diagnosis and treatment **every working day**	58,300

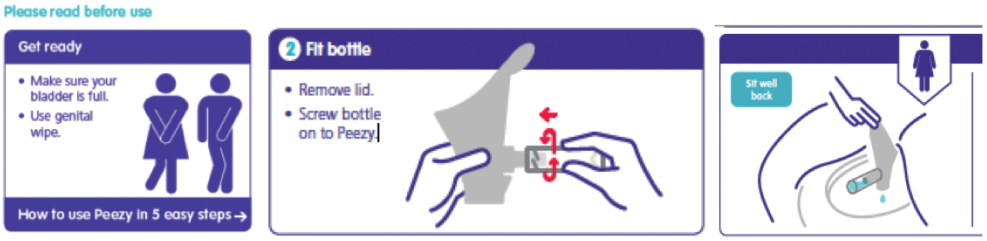
Annual number of failed urine tests
14,627,000

- Unplanned Admissions Committee: 134,000 elderly patients in hospital annually, due to untreated UTI. These episodes cost the NHS over £400m to treat;
- 50% of the global rise of AMR has a urinary source;
- 47% of blood infections that can lead to Sepsis have a urinary source;
- Unnecessary antibiotic prescribing when pregnant can negatively impact the long-term health of both mother and the unborn.

Peezy Midstream: how Dr Vincent Forte solved the problem.

Peezy Midstream is a highly engineered funnel designed to capture only midstream urine (also known as clean-catch). It is held close to the body; the patient urinates in one flow. The device rejects first-void urine into the loo, captures midstream and releases overflow into the loo. The device is shown to reduce specimen contamination to as low as 0%, saving GP surgery 60% on lab spend. Designed by a Doctor, Peezy Midstream is innovative, low-cost and the first of its kind in the world. Made in Kent, UK, it could have saved the NHS around £80m on retesting alone, before efficiency savings were brought into the equation.

In recognition of the device efficiency in the short and long term, Peezy Midstream has been granted a US Medicaid HCPCS (reimbursement) code refunding US$48-US$63. It has started to be adopted by the US Military.

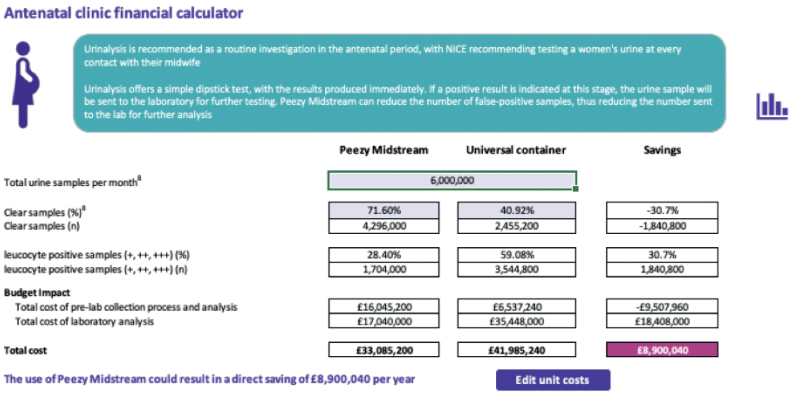


Health setting / healthcare provider	Contamination rate	Midstream rate	Patient number
Barts Health NHS Foundation Trust Urology	23%	1.5%	66
Pennine Acute Hospitals NHS Foundation Trust Urology	23%	5.0%	104
Royal Surrey County Hospital Antenatal	9%	2.5%	26
Watford General Hospital Antenatal	35%	1.5%	469
Watford General Hospital Antenatal	70% reduction of false-positive antenatal specimens: adoption implemented		
North Devon NHS Trust Urology & Antenatal*	25%	1.0%	100
NHS National Institute for Health Research			**Usability Study**
Instructions clearly explained		100%	
Peezy collects midstream easily		94%	
Patients confident using Peezy		94%	

An FOI request to all NHS Trusts in 2006 revealed specimen contamination ranging from below 1% to over 70%.

Urine has diagnostic parity with blood yet healthcare policymakers resist creating a protocol for its collection.

Cost savings using antenatal figures only



What has impeded Peezy Midstream uptake in the NHS?

- Silo budgets: disconnect between funding prevention over cure;
- Apathy, inertia and resistance to change at ground level, seen in failed pilot studies in different clinical settings together with "academic" studies that fail to follow protocol with appropriately inaccurate results. Real world evidence outcomes are a stark contrast!
- No incentive for labs to improve first-time outcomes as they are paid per specimen not on efficiency;
- Guidelines for AMR stewardship arenot being applied to the area of specimen collection where over prescribing is most prevalent;
- Typical procurement response below … *note the two-year time lapse between the procurement officer being presented with business case and response to adoption discussion*:

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